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ABSTRACT

This volume is a collection of background papers and materials prepared for workshop participants engaged in empirical research on the topic of "informed consent with subjects of uncertain competence." The first three papers consider the minimum competence needed to consent to or refuse participation in research, including a philosophical overview, a legal overview, and a psychiatric overview. The fourth paper, a review of the literature for empirical studies on competence and consent, highlights questions which have not been addressed as well as findings which require replication and further investigation; a supplementary, expanded bibliography follows this paper. The final paper is a summary of the workshop discussion in which participants identified an agenda for future research, including the five major areas considered most deserving of attention and practical methodologic considerations for investigators planning research in these areas. The appendix contains a brief paper describing new implications for informed consent, a presentation of the regulations on consent, the original workshop agenda, and a list of workshop guests. (Author/NRB)

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ED211874

COMPETENCY AND INFORMED CONSENT

Papers and Other Materials Developed for the Workshop "Empirical Research on Informed Consent with Subjects of Uncertain Competence"

January 12 - 13, 1981

Rockville, Md.

Edited by: Natalie Reatig
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Alcohol, Drug Abuse, and Mental Health Administration

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Preface

The Pharmacologic and Somatic Treatments Research Branch was pleased to sponsor this workshop in keeping with its commitment to provide and encourage the development of information concerning ethical issues in research with human subjects.

The workshop's title, "Empirical Research on Informed Consent with Subjects of Uncertain Competence" was carefully chosen to reflect its scope. It was a 'workshop' - not a conference; the participants were talking to each other rather than to an audience. They were invited to discuss their work in progress and to consider possible areas for collaboration. The focus was upon 'empirical research' - data derived from controlled and systematic studies rather than from anecdotal reports or theoretical analyses. The population was 'subjects' - persons who are the focus of research inquiry - rather than patients in a treatment setting. And, finally, the term 'uncertain competence' was developed to describe persons whose ability to make decisions on their own behalf is not ascertained at the time of entry into consent negotiations. It was considered a term with the least pejorative implications.

The participants were invited on the basis on their interest in and contributions to the focal topic. (See List of Participants for relevant publications and activities). Invited guests included research associates of the major participants, investigators planning or currently engaged in related research enquiries, public officials having policymaking or advisory roles in the development of guidelines or regulations for the protection of human subjects in research, and NIMH staff from extramural grants programs and review committees. (See List of Invited Guests in Appendix.)

One of the most important features of the workshop was the opportunity for participants and guests to engage in an informal exchange of information and of ideas concerning research strategies. It is hoped that the benefits of this sharing will become manifest in a higher quality of research more clearly focused on and targeted to resolution of the problems identified.

TABLE OF CONTENTS

			Page
1.	Introduction	Natalie Reatig	1
2.	List of Invited Participants		4
3.	Prepared Papers: WHAT WOULD IT MEAN TO BE COMPETENT ENOUGH TO CONSENT TO OR REFUSE PARTICIPATION IN RESEARCH?		
	Philosophical Overview	Bernard Gert Charles Culver	12
	Legal Overview	Alan Meisel	32
	Psychiatric Overview	Paul Appelbaum Loren Roth	72
4.	EMPIRICAL STUDIES ON COMPETENCE AND CONSENT: A Review of the Literature.	Barbara Stanley	106
5.	INFORMED CONSENT AND COMPETENCE: A Bibliography (Special Emphasis upon Psychiatric Research)	Natalie Reatig	133
6.	AN AGENDA FOR RESEARCH ON COMPETENCY TO CONSENT: A Summary of The Workshop Proceedings	Ruth Faden	160
7.	APPENDIX DHHS REGULATIONS AND PSYCHIATRIC RESEARCH: New Guidelines for Informed Consent	Natalie Reatig	165
	DHHS Regulations 45 CFR 46 A (Informed Consent)		171
	Agenda of the Workshop		178
	List of Invited Guests		179

Introduction

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In January of 1981, the Pharmacologic and Somatic Treatments Research Branch of the National Institute of Mental Health sponsored a workshop for investigators currently engaged in empirical research on the topic "Informed consent with subjects of uncertain competence". The National Institute of Mental Health supports a large number of research grants involving individuals characterizable as of "uncertain competence". These persons fall within the broad definition of "mentally disabled", defined by proposed DHHS regulations as "those who are mentally ill, mentally retarded, emotionally disturbed, psychotic or senile", (See Federal Register: 43:223:53954, 1978). A major concern for investigators conducting research with these populations is how to distinguish between subjects who are capable of giving consent on their own behalf and those who are not.

Informed consent from subjects is a normative requirement in most research supported by the DHHS. Federal regulations describe the circumstances under which this consent must be obtained and list items of information considered sufficient to meet standards for adequate disclosure (See Appendix). The regulations mandate that consent be obtained from "competent" subjects but there is no guidance available to assist those who are delegated responsibility for determining competence.

It remains unclear whether the more traditional legal and psychiatric criteria are appropriate in the research setting as compared with the criminal trial or treatment setting. Should there be universally applicable competency criteria or should there be performance criteria tailored to meet specific situations or individual abilities? Should the standard for competency be flexible according to the degree of risk inherent in the proposed research? We still know very little about the process of decision-making in the research setting. What motivates subjects to consent to or refuse research participation? What underlying values influence investigators, family members or delegated representatives in their determinations of another's competency? We need to identify and understand the multiple factors that influence, hinder and enhance both of these decision-making processes.

The workshop goals were 1) to evaluate the current status of empirical research about competence and informed consent; 2) to identify and target problem areas in need of further inquiry; and 3) to discuss and explore development of appropriate resources and methodologies for use in such research. To enhance the quality of the discussion a number of background papers were prepared in advance and circulated to all participants. These papers and some additional materials have been collected here with the intention of stimulating interest in and encouraging research on the topic of competency and consent.

The first three papers address the question, "What would it mean to be competent enough to consent to or refuse participation in research?".

The authors were asked to identify the range of practical and theoretical conditions of competence sufficient to consent from the perspective of their separate disciplines. Bernard Gert and Charles Culver provide the philosophical overview, Alan Meisel the legal overview and Paul Appelbaum and Loren Roth the psychiatric overview.

The fourth paper presents a review of the literature for empirical studies on competence and consent. In her review, Barbara Stanley highlights some questions which have not been addressed and some findings which require replication and further investigation. I have exercised the editorial liberty of appending a supplementary, expanded bibliography to complement the author's assigned focus upon empirical research.

The final paper is a summary of the workshop discussion in which participants were asked to identify an agenda for future research. Ruth Faden, the workshop co-chair, lists the five major areas which emerged as most deserving of attention and offers some practical methodologic considerations for investigators planning research in these areas.

The Appendix contains 1) a short paper describing some new implications for informed consent offered by recently promulgated DHHS regulations; 2) a presentation of the regulations on consent, listing the items of information required for disclosure, the circumstances under which these may be waived or altered, the requirements for documentation of consent and the circumstances under which these may be waived; 3) the original workshop agenda; and 4) a list of the workshop invited guests.

It is hoped that these documents will be useful and provocative. This workshop has made a beginning - there is much that remains to be done!

INVITED PARTICIPANTS, WORKSHOP: EMPIRICAL RESEARCH ON
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Relevant Publications:

Appelbaum, P.S. & Gutheil, T.G. Rotting with their rights on: Constitutional theory and clinical reality in drug refusal by psychiatric patients. Bull. Am. Acad. Psychiat. Law. 1979, 7:308-317.

Appelbaum, P.S. & Gutheil, T.G. Drug refusal: A study of psychiatric in-patients. Am. J. Psychiat. 1980, 137:340-346.

Appelbaum, P.S. & Bateman, A.L. Competency to consent to voluntary psychiatric hospitalization: A theoretical approach. Bull. Am. Acad. Psychiat. Law. 1980, VII:4:390-400.

Appelbaum, P.S., Mirkin, S.A. & Bateman, A.L. Competency to consent to psychiatric hospitalization: An empirical assessment. Am. J. Psychiat. (in press).

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Relevant Publications:

Beauchamp, T.L. & Childress, J.F. Principles of Biomedical Ethics. Oxford University Press, 1979.

Beauchamp, T.L. "The foundations of ethics and the foundations of science". In: H. T. Engelhardt, Jr. and D. Callahan (Eds.) The Foundations of Ethics and its Relationship to Science. Vol. IV. Hastings, N.Y.: The Hastings Center, 1979. pp. 260-268.

Beauchamp, T.L. Ethical Theory and the Problem of Closure. In: D. Callahan, A. Caplan and H.T. Engelhardt, Jr. (Eds.) Closure of Scientific Disputes. Hastings Center: Hastings-on-Hudson. 1981.

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Culver, C.M., Ferrell, R.B., & Green, R.M. ECT and special problems of informed consent. Am. J. Psychiat. 1980, 137:586-591.

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Relevant Publications:

Faden, R.R. Disclosure and informed consent: Does it matter how we we tell it? Health Education Monogr. 1977, 5:3:198-215.

Faden, A.I. & Faden, R.R. Informed consent in medical practice: with particular reference to neurology. Arch. Neurol. 1978, 35:761-764.

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Gray, B.H., Cooke, R.A. & Tannenbaum, A.S. Research Involving Human Subjects. Science. 1978 201:1094-1101.

Gray, B.H. Complexities of informed consent. Annal. Amer. Acad. Pol. Sci. 1978, 437:37-48.

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Meisel, A. Rights of the mentally ill: The gulf between theory and reality. Hosp. & Commun. Psychiat. 1975, 26:6:349-353.

Meisel, A. Informed Consent: Who decides for whom, when, and if. In: Medical Ethics and the Law: Implications for Public Policy. Hiller (Ed). Ballinger Publishing Co. (in press).

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Relevant Publications:

Mellinger, G.D., Huffine, C.L., & Balter, M.B. Assessing comprehension in a survey of public reactions to complex issues. Oakland, CA: Institute for Research in Social Behavior. June, 1980.

Mellinger, G.D., Huffine, C.L. & Balter, M.B. Judgments about ethical issues in biomedical research: Methods and findings of developmental studies. (Ethical Issues Monograph Series No. 1) Revised, 1980.

Huffine, C.L., Mellinger, G.D. & Balter, M.B. Some effects of an educational questioning strategy on responses to complex questions. Oakland, CA: Institute for Research in Social Behavior, April 1980.

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Roth, L.H., Meisel, A., & Lidz, C.W. Tests of competency to consent to treatment. Amer. J. Psychiat. 1977, 134:279-284.

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Stanley, B., Stanley, M., Lautin, A., Kane, J., Schwartz, N. Preliminary findings on psychiatric patients as research participants: A population at risk? Amer. J. Psychiat. (in press)

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COMPETENCE TO CONSENT: A PHILOSOPHICAL OVERVIEW *

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*Revised from a chapter to appear in Philosophical Problems in Medicine and Psychiatry, Oxford University Press, (in press).

Competence to Consent: A Philosophical Overview

Obviously we are primarily concerned with the concept of competence because it is directly relevant to the question of valid consent, but we believe that there is no special sense of competence which is related to valid consent. Rather the concept of competence remains the same, namely, having the ability to perform those tasks that someone (in that position) is supposed to have, though since it is always related to some particular task or group of tasks, the criteria for determining whether or not someone is competent to perform that task is determined by the nature of the task. Thus we shall begin by analyzing the general concept of competence, and then we shall relate it to the problem of valid consent.

The sentences "John is competent" and "John is incompetent" do not express complete statements. Of course, the context may make it clear what is being expressed by these sentences. For example, if we are discussing whether or not to hire John to do our taxes, it is quite clear that the sentence "John is incompetent" means John is incompetent to do one's taxes. But not all incompetence is attached to offices or positions or jobs. Someone can be incompetent in what might be regarded as a more fundamental sense, namely he may be incompetent to perform some activity that almost all normal adult human beings can perform.

This is not really a different sense of incompetence, it is rather that the person is incompetent to do more fundamental activities than those involved in some specific office or job. For example, a person may be incompetent to feed himself. He may simply be unable to figure out what or how to eat. The sense of incompetence here is exactly the same as that which is involved in filling out tax returns. In both cases there is a specific task to be performed and a person who is unable to perform that task. The only difference, and it is a big practical difference, is that only those who occupy some position involving the making out of tax returns count as incompetent when they cannot do so, whereas anyone who cannot understand how to feed himself is regarded as incompetent.

But though competence always involves the ability to do some particular task, competence is not merely a synonym for ability. If someone cannot run a marathon, we do not say that he is incompetent to run a marathon, rather we say that he lacks the physical ability to do so. Competence involves mental or volitional rather than physical abilities. But lack of such abilities does not by itself involve incompetence. If one does not have the mental ability to do theoretical physics it would at least be misleading to say that they were incompetent to do theoretical physics, unless they were in some position in which it is expected that they have that mental ability. To return to our first example, when we say that John is incompetent to do one's taxes, this implies that John is an accountant or has a job that involves making out tax returns. It is only with accountants, etc. that lack of ability to make out tax returns counts as incompetence.

As noted before, to say of someone that he is incompetent demands a context. A person is not simply incompetent; he is incompetent to do x, or x and y, or x,y, and z, etc. It is possible for someone to be incompetent to do any of the things that a normal adult human being can do: new born infants are incompetent in this total way, and so are some adults. We can regard them as totally incompetent and no philosophical problems arise in determining that they are incompetent with regard to any task, no matter how described. Philosophical problems arise in deciding whether someone who is competent to do some things is competent to do a particular kind of action, or make a particular kind of decision. How is one to decide these issues? Here it should be noted that the more precisely described the activity is, the more likely it is that one can decide whether or not someone is competent to perform that kind of activity. Suppose that we are wondering whether someone is competent to make a will. It is a necessary condition for being competent to do this that one know what is involved in making a will: one must understand, at least in its practical sense, what a will is. If one is not aware of what is involved in making a will, then one is incompetent to make a will. In general, in order for one to be competent to do x, one must have at least a practical understanding of what it is to do x. One must also understand when one is doing x; it is not enough to know what wills are, one must also be able to understand when one is making a will. It seems that two necessary features for being competent to perform an activity are that one understands what that activity is and knows when he is participating in it. With regard to giving consent to participation in an experiment one must know what it is to give such consent and know when one is giving such consent. These however are only necessary features for competence to give valid consent, they are not sufficient features.

We may then tentatively define incompetence in the following way: A person is incompetent to do x, if it is reasonably expected that any person in his position, or any normal adult human being can do x, and this person cannot do x. And his inability to do x is not due to a physical disability. A person is competent to do x, if he is not incompetent to do x. It is important to note that in this sense of incompetence, nothing is being implied about how one ought to treat a person who is incompetent to do x, except, of course, that if one wanted to get x done, one should not entrust the job to someone who was incompetent to do x. Even with regard to someone who is incompetent to do something that every normal adult human being is expected to be able to do, nothing more is implied than that it would be unreasonable to entrust that person with the task of doing x. So that if someone is incompetent to handle money at all, it would be unreasonable to give him some task that involved his handling money, but if he has money of his own, nothing follows about prohibiting him from spending it, or giving it away, or doing anything else he may want to do with it. We are not automatically justified in preventing someone from doing something simply because he is incompetent at doing it. If someone is an incompetent poker player, e.g. he does not know what hand beats another, it does not follow that anyone is justified in prohibiting him from playing poker if there are others who are willing to play poker with him. However, if the consequences of his playing are serious enough, one might be so justified. Similarly, if someone is incompetent to make a decision about some medical treatment, it does not follow that someone else is thereby justified in making that decision for him. It may be that someone is so justified, but that he is does not follow solely from the fact that the person is incompetent to make the decision himself but depends upon other matters as well.

Incompetence, in the sense that we have been discussing it, is almost completely an empirical matter and is not identical with what for the sake of clarity we shall call "legal incompetence". To be declared legally incompetent to do x depends upon a judgement of incompetence in the sense that we have been discussing, but it also involves something else, namely a decision that someone else is justified in acting on that person's behalf with regard to doing x, and that he may justifiably require, prohibit, permit, etc. actions with regard to that person. Normally a judgment of legal incompetence to do x, only involves incompetence to do those things that all normal adult human beings are expected to be able to do. That is, it is persons who cannot feed or clothe themselves, or who cannot handle money, whom we declare legally incompetent and then sometimes give to some other person, a legal guardian, the authority to make decisions for them.

We also sometimes declare persons legally incompetent to perform certain professional tasks; however in these cases we do not appoint a guardian to make decisions for them. Thus someone who has a position as a lawyer or doctor may, for various reasons, become unable to perform the professional tasks required of him. It may be appropriate in some of these instances for the person to be declared legally incompetent to perform those tasks. In this case no guardian would be appointed, but the person would be prohibited from performing that activity which he performed incompetently.

The important issue in going from empirical incompetence to legal incompetence is whether one can justify the restriction of freedom involved in such a judgment. We will not discuss the justification of such interference for the person's own good here, but will only say that such a justification involves the prevention of the suffering of significant evils.[1]

COMPETENCE TO CONSENT TO TREATMENT OR PARTICIPATION IN RESEARCH

Given this general discussion of competence and incompetence let us now try to apply it to the problem of valid consent. What is involved in saying that someone is incompetent to give valid consent? We believe there are two levels of incompetence and that it is useful to distinguish clearly between them.

1. There is a category of patients who are unable to give or refuse consent at all. Some patients in this category are completely unaware of their surroundings and are not able to understand any question that might be asked of them--for example, infants, patients in a coma, or patients who are severely retarded or senile. For such patients, nothing that they say or do could even count as consent or refusal of consent. They may be called "totally incompetent" and it is universally acknowledged that it is justified, even morally required, for someone else to make decisions for them and on their behalf.

   However there are some patients who fit in this first category who are less than totally incompetent. They may have very limited cognitive abilities, may be able to ask for food, or for relief from pain, and yet be unable to understand any questions not directly related to present stimuli. Therefore they do not understand at all the request for consent to a medical procedure: either therapeutic or experimental, they do not know what is being asked of them and do not realize in fact that they are being asked to give consent. For these patients, as for those who are totally incompetent, it seems appropriate and morally justified for someone else to be authorized to give or withhold consent on their behalf. For example, consider the following case:

> Case 3-1. Ms. B, a 69-year-old woman with a biopsy-proven unresectable retroperitoneal sarcoma, was admitted to our unit in a profound confusional state that was thought to be the result of delirium, a very severe psychotic depression, or a combination of the two. Approximately 1 year earlier she had been admitted to the hospital with a similar mental syndrome. At that time a retroperitoneal mass had been identified and biopsied during laparotomy. Treatment with ECT at that time (1 year before the present admission) resulted in dramatic clearing of her confusional state and melancholia, enabling Ms. B to resume a satisfying life with her family for a period of about 10 months, when the current confusional state developed.
>
> At this point Ms. B was disoriented to place and time and was severely agitated and restless. She was not able to give understandable answers to most direct questions, and in general her speech consisted of incoherent babbling. An extensive search for a metabolic, pharmacologic, or structural cause for her mental syndrome yielded no positive results. Her retroperitoneal sarcoma appeared to have increased somewhat in size, but this could not be directly correlated with her change in mental function. Her sarcoma was in no way felt to be immediately life-threatening. Her physicians felt that ECT was again indicated but that she was incompetent to give even simple consent to any treatment procedure. The hospital attorney was of the opinion that ECT could be used if the unanimous consent of her three adult children were obtained. Her children did consent, and a course of ECT was again administered. A similar gratifying improvement resulted.

We will refer to patients in this category as being incompetent to give (even) simple consent. The concept of "simple consent" is explained in the description of the next category of patients.

2. This second category of incompetent patients we refer to as being incompetent to give valid consent. They are however competent to give simple consent; i.e. they understand that they are being asked to consent to a medical treatment or an experimental procedure and can give consent or refuse to do so, but they lack the ability to understand or appreciate the information that is necessary to give a valid consent. The clearest example of someone who fits this category is a patient who is moderately delirious or demented and is aware of only some aspects of his situation. He may perfectly well understand that he is being asked for consent to perform some medical procedure but may not know where he is, or who is asking for his consent, or why they are asking for it. For example, he may know nothing whatsoever of the reasons why consent is being asked and/or he may disbelieve most or all of what he is told about the consequences of his giving or refusing that consent. This person differs from the persons discussed in the first category in that he may give his consent to a treatment, or vigorously refuse to give it. But both the refusal and the granting of consent do not count as valid, for such a person is unaware of sufficient information to give valid consent. We will say of such a patient that he is competent to give or refuse simple consent, but is

incompetent to give or refuse valid consent.

Another interesting example of patients in this category are those who have delusions which are relevant to the matter of giving or withholding consent. Suppose that someone has the paranoid delusion that all of his doctors are part of a plot to take over his body and that regardless of what his doctors are saying, if he gives his consent they will perform some procedure that will give them complete control over his thoughts and actions. He believes this even though consent is only being requested for a diagnostic procedure completely unrelated to his delusion, e.g. a biopsy to determine if a tumor is malignant. We want to maintain that such a person is competent to give simple consent, but is incompetent to give valid consent, because he is unable to understand or appreciate the information that is necessary for valid consent. This does not mean that we are thereby justified in performing the biopsy independent of his valid consent. For this to be true, one must apply the justification procedure that we allude to in footnote 1.

A patient may have a delusion which results in his giving rather than in withholding consent. Suppose that a man believes that he has been given superhuman powers and that, like Superman, nothing done to him on earth can harm him in the slightest way. Thus when he is asked for his consent to participate in a serious and risky experiment he readily gives his consent for he does not believe that there is any risk whatsoever for him. In such a case we would say that his simple consent is not valid for he is incompetent to give valid consent. We say this for the same reason we gave above, he is unable to understand or appreciate the information necessary for valid consent.

If someone is not given adequate information, he cannot give valid consent, for he does not know enough about what he is consenting to. But clearly the important matter is not merely some mechanical procedure of providing information to someone. Suppose a doctor or researcher has developed what is universally acknowledged as an ideal presentation of all the information required for valid consent for a certain medical problem. Now suppose that he presents this information to his patient in a way that all his fellow doctors regard as clear and non-biased. Does the patient now have the information required for valid consent? We don't know. It depends upon what the patient understood. If the patient has only a very limited command of English, then providing the information in English will not provide the patient with adequate information to give valid consent. Similarly if the patient is suffering from such anxiety that he can understand little of what is being told him, he does not have adequate information to give valid consent. This is why it may be important that nurses, or someone who has the opportunity to talk to the patient at some length, be required to determine that the patient does indeed have adequate information to give valid consent.

Thus a patient may be incompetent to give valid consent because he cannot understand anything as complex as the information required for valid consent, e.g. in the case of a retarded person or a young child, or the person may not be able to appreciate the information he is provided because, for example, he is suffering from delusions. A completely senile person and a very young infant would be incompetent to give even simple consent; the person with delusions would be incompetent to give valid consent. A slightly older child might be competent to give simple consent but incompetent to give valid consent. In general one might say that when we can straightforwardly determine that the person doesn't understand any of the information being provided, he is incompetent to give simple consent, and when he understands some but not enough information or doesn't appreciate it, he is only incompetent to give valid consent.

It is fairly straightforward to determine whether or not someone understands the information that is presented to him, though, of course, there will always be borderline cases. When dealing with appreciating the information, we have a trickier situation. As we use the term "appreciate", it requires more than understanding. Someone can understand but not appreciate the information given. For example, someone with paranoid delusions that involve his doctors may understand all of the information presented to him, but because of his false beliefs about his doctors he cannot properly evaluate that information and thus cannot give valid consent. Failure to appreciate, like failure to understand, must be determined prior to consent or refusal of consent. A refusal of consent, even if irrational, is not sufficient to show a failure to appreciate the information. It is because there may be a temptation to treat irrational refusal of treatment as incompetence to give valid consent (because of failure to appreciate relevant information) that we require refusal by someone incompetent to give valid consent to be accorded the same safeguard as someone who is incompetent but irrationally refuses treatment.

Thus there is a significant practical difference between the two kinds of incompetence. With incompetence to give simple consent, nothing the person does counts as either the giving or the refusing of consent. In this case there is no overruling of the patient's decision, there is no decision of the patient's to overrule. With incompetence to give valid consent, the problem is more complex. In such cases the patient can either give or refuse simple consent, but since they are incompetent to give valid consent, obviously their consent is no more valid than their refusal. In these cases, one must decide what to do. Our suggestion is that these cases be divided into two main categories, (1) those in which the person gives simple consent but in which we believe that he is incompetent to give valid consent and (2) those in which the person gives a simple refusal of consent but in which we also believe that he is incompetent to give a valid refusal of consent.

In the first category we believe that a guardian should be appointed and that he should decide on behalf of the patient whether or not to accept the proposed treatment. If he agrees with the patient, there is no problem at all, if he does not agree, a problem does seem to arise, for then the guardian seems to be overruling the patient's decision. And this kind of action seems paternalistic and thus in need of justification. However this is not the case. The guardian is not overruling the patient, rather he is refusing to make a decision that he believes is not in the patient's best interests. It is true that the patient is not getting a procedure or treatment that he has given simple consent to, but if the patient is genuinely incompetent to give valid consent to that procedure or treatment, then he does not really appreciate what he is consenting to. Thus we are not depriving the patient of something he wants, rather we are simply refusing to provide something we don't think is in his interests.

The second case, where the patient gives a simple refusal of consent, is somewhat different. Again we suggest that a guardian be appointed to decide, on behalf of the patient, whether or not to accept the proposed treatment. If he agrees with the patient concerning refusal of consent, again there is no problem, but if he does not agree and thinks that the proposed treatment is in the patient's best interest, then there is a serious moral problem. To allow the guardian to consent to treatment when the patient has refused it, even though, by hypothesis the refusal is due to a failure to appreciate the situation, is to allow one person to act paternalistically with regard to another, simply on the grounds that the first is incompetent to give valid consent. We do not think these are adequate grounds in and of themselves. We believe that even with regard to patients incompetent to give a valid refusal of consent, their simple refusal of consent must be taken very seriously and overruled only in special circumstances, when the failure to treat would result in significant evils being suffered. It is an act of paternalism and has to be justified just like any other paternalistic act.

We obviously think that just as with competent patients, so with those incompetent to give valid consent, it is a much more serious matter to treat without consent of the patient, than not to treat even though a simple consent has been given. In the former case we actively impose something on the patient, in the latter case we simply refuse to do something agreed to by the patient. Thus we give a simple refusal of consent for treatment, by a patient incompetent to give a valid refusal of consent, much more weight than a simple consent by the same patient. This seems to reverse the traditional procedure where a simple consent by such a patient is sometimes taken to be valid, and a simple refusal of consent is all too easily overruled.

THE COMPETENCE OF PSYCHIATRIC PATIENTS TO CONSENT TO TREATMENT OR RESEARCH

Some might question whether patients suffering from mental maladies are in general incompetent to give or refuse to give valid consent to proposed treatments or experiments. We believe that the overwhelming majority of such patients are quite competent to give valid consent and that, in fact, one is much more apt to find incompetence to give valid consent among patients found, for example, on neurosurgery and oncology wards.

The case of Ms. B discussed above does represent a patient who was incompetent to give even simple consent to treatment because of her thorough confusion and incoherence. One does encounter other such patients in psychiatry who, because of, say, drug delirium or acute severe psychosis, are unable to give or refuse even simple consent. Though such cases are dramatic they constitute only a small percentage of psychiatric cases. We believe the incidence of this kind of incompetence is much higher in selected medical and surgical patient populations. This would be an interesting and important topic for future empirical research. At any rate, when one does encounter a patient incompetent to give or refuse simple consent, then it is usually morally acceptable to rely on next-of-kin or court-appointed guardian for consent, whether the patient is suffering from a mental or a physical malady.

Patients who are competent to give simple consent but incompetent to give valid consent are probably encountered somewhat more often among psychiatric than other patients, though this subject also would benefit from empirical research. Patients who have delusions directly related to the treatment or consent process are of course apt to be patients with mental maladies, though, again, their absolute numbers are very small. Perhaps somewhat more frequently one encounters psychiatric patients whose mental confusion, associated with a psychosis, makes their understanding and appreciation of the consent information sufficiently suspect that one questions whether the consent they give or refuse is valid. Clearly, one cannot overrule the refusal of consent of these patients without a strong justification, but as mentioned above it seems appropriate in such cases that a guardian be appointed to give valid consent on behalf of the patient even when the patient has given simple consent to the proposed treatment or experiment.

However, we believe the overwhelming majority of psychiatric patients are competent to give valid consent. These patients understand if something is wrong with them and are capable of understanding the nature of the available treatments and the risks and the benefits associated with each; they can also evaluate the personal risks and societal benefits of various experiments. There is nothing inherently more suspect about a patient consenting to a treatment to relieve mental pain than consenting to relieve physical pain. There is (or should be) no coercion present in either case. In fact we suspect that there is probably more valid refusal of treatment among psychiatric patients than among selected medical or surgical patients. As a group psychiatric patients may be more capable of withstanding pressures from their doctors to consent than are seriously ill medical or surgical patients, though we have no data on this point.

When psychiatric patients do refuse treatment, whether they are or are not competent to give valid consent, that refusal is frequently seen as irrational by the treatment team. We think it is important to distinguish patients who are incompetent to give valid consent from those whose refusal is regarded as irrational. (There is usually no irrational consent, for doctors would not propose a treatment that was irrational.) We should be able to determine incompetence to give valid consent prior to the giving or refusing of consent; irrational refusal obviously can only be determined after the refusal. We propose that irrational refusal of treatment never be taken as a sign of incompetence to give valid consent, if the patient's giving of consent would have been regarded as valid. This does not mean that it is never morally justified to overrule valid but irrational refusal of treatment, but one should be clear about what one is doing. One advantage of being clear in such cases is that a change of mind (perhaps due to the persuasive abilities of the psychiatrist) by a competent patient who has previously validly but irrationally refused treatment can now be taken as valid consent; whereas if the patient had been regarded as incompetent to refuse valid consent, their subsequent consent would still not be valid.

1. See "The Justification of Paternalism" by Bernard Gert and Charles M. Culver ETHICS Vol 89, No. 2; January 1979: pp 199-210.

WHAT WOULD IT MEAN TO BE COMPETENT ENOUGH TO CONSENT TO OR REFUSE PARTICIPATION IN RESEARCH:

A LEGAL OVERVIEW

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"Empirical Research on Informed Consent/With Subjects of Uncertain Competence"

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What would it mean to be competent enough to consent to or refuse participation in research?

We cannot begin to answer this question without first appreciating the context in which it arises. Before we can intelligently discuss it, we need to know why it is a question worth asking, and answering.

The concept of incompetency--I will use this negative term rather than the positive term competency --is extremely murky as far as law is concerned. Despite the long scholarly exegeses of the subject, the many mentions and uses of the term in the case law, and its increasing appearance in statutes and regulations, confusion still abounds about incompetency. I do not propose to set the record straight, nor to cure all of the evils today. Instead, I hope to establish a structure for thinking and talking about competency and incompetency, so that we may have a common language and set of ideas to work with in attempting to better understand the concept.

At the outset, it is perhaps best to indicate what the scope of my concern is. The concept of incompetency arises in various areas of law: the criminal justice system, the administration of decedents' estates, and the enforcement of contractual obligations are a few of the more obvious ones. I do not intend to deal with any of these, but only with incompetency in the medical decision-making process.

In the medical decision-making process, as in the other areas of law in which incompetency plays a role, there are two different kinds of incompetency: "de jure" and "de facto." De jure incompetency results from a determination by a court that an individual is incompetent (usually referred to as an "adjudication" of incompetency). An individual who is adjudicated incompetent is de jure, or legally incompetent. Ordinarily, a guardian is appointed to make for the individual those decisions which the individual himself is incompetent to make. The adjudication may be plenary or it may be partial; in the former case, the individual is deprived of all decisional authority of legal significance, but in the latter case, the individual is deprived only of decisional authority in a narrow area. (There is one other group of persons who are de jure incompetent but whose status as such does not result from the action of a court. This is, of course, persons under the legal age of majority. Usually a child needs no guardian appointed as his parents are his natural guardians.)

I will not, in this paper, unless specifically indicated, be discussing persons who are de jure incompetent--either minors are adjudicated incompetents. Rather, I will deal only with those persons who are de facto incompetent--that is, persons who are thought by medical authorities to be incompetent in fact to participate in making decisions about medical treatment or research. Ultimately, regardless of whether the decision-maker is a judicial or medical authority, some means of determining who is incompetent will have to be devised. Thus, the conceptual problem involved in both kinds of incompetency will turn out to be the same. Before we reach this conceptual problem, however, we need to know something about the legal model of the medical decision-making process which is the larger context in which the problem of incompetency arises.

THE LEGAL MODEL OF MEDICAL DECISION-MAKING

Law starts with the presumption that every individual has a right to make medical decisions for his or her own care--what I will refer to as the right of decisional autonomy. This right has deep roots in the common-law tradition and more recently has found positive sanction in the constitutional right of privacy as well. Regardless of its source, the right of decisional autonomy is implemented today through what is referred to contemporarily as the requirement of "informed consent." That is, before a medical procedure may be performed by a physician on a patient, the physician must obtain the patient's "informed consent" to treatment.

Informed consent is also required before an individual may participate in "research" procedures, whether those procedures are intended to be beneficial to the subject or not. The source of the requirement of informed consent to research is two-fold: it, too, is mandated by common law, and it is mandated by regulations issued by the Department of Health and Human Services pursuant to federal statutory authority.[1]

The right to decisional autonomy, as with all other rights, is not absolute. Another way of stating this is that there is a presumption of decisional autonomy, but this presumption may be overcome in certain situations. A good starting point both for a discussion of the role of incompetency in medical decision-making and of the situations in which the presumption may be overcome is Judge Cardozo's dictum that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[2] The presumption of decisional autonomy is laid out straight away: "Every human being . . . has a right to determine what shall be done with his own body." The conditions under which the presumption can be overridden are not specifically stated, but are clearly implied: when an individual is not of "adult years" or not of "sound mind," he is not permitted to exercise decisional autonomy. Thus, certain persons are disqualified from exercising decisional autonomy by virtue of their age. This is an objective criterion, not a functional one. There are clearly some persons who are not adult in years but who are adult in their ability to function in the world; and the converse is equally true. Other persons are disqualified from exercising the right of decisional autonomy by virtue of their mental qualities. Whether this criterion is one based on status or function is not immediately clear. Indeed, it is the heart of the matter with which we are concerned, and for the remainder of this discussion, I will be equating, at least loosely, incompetency with the "unsoundness of mind" referred to by Cardozo.[3]

IMPLEMENTATION OF THE RIGHT OF DECISIONAL AUTONOMY: THE REQUIREMENT OF INFORMED CONSENT

The individual's right of decisional autonomy in matters medical is implemented through the requirement that a doctor obtain a patient's "informed consent" to research and treatment.

Informed consent to treatment is an outgrowth of the earlier requirement that a doctor must obtain a patient's "consent" to treatment, which is itself an outgrowth--or more properly, an illustration--of the ancient common-law protection accorded to bodily integrity by the law of trespass. If one were "touched" by another without consent, that touching constituted a trespass to the person, otherwise known as a battery. Even if no physical harm results, the non-consensual nature of the touching makes it a legal wrong for which redress might be obtained under a writ of trespass. Indeed, not only was absence of physical harm no barrier to legal redress, a touching that benefited a person might be grounds for a lawsuit as long as it was non-consensual.

Informed consent to research has its origins primarily in the Nuremberg trials following World War II, in which several German physicians, in cooperation with the government, performed medical "experiments" on prisoners of war and concentration camp detainees. One aspect of the Nuremberg judgment, referred to as the Nuremberg Code, promulgates requirements for the ethical conduct of medical experimentation, one of which is informed consent.[4] Subsequently, the World Health Organization in its 1964 Declaration of Helsinki also subscribed to the requirement of informed consent to experimental procedures if the subject is competent and from the "legal guardian" if the subject is not.[5]

It was not until 1966 that the U.S. Public Health Service incorporated the substance of the Nuremberg Code and the Declaration of Helsinki into guidelines for researchers, which were then modified and published as the "Institutional Guide to DHEW Policy on Protection of Human Subjects" in 1971. This then became the basis for the DHEW regulations for the protection of human subjects, first issued in 1973, and amended several times since then.

Just what must be done to obtain a patient's "informed consent" to research and treatment is a matter of much dispute and debate. What cannot be gainsaid are two things: certain information must be provided the patient by the doctor, and the patient must give permission for the medical procedure to be rendered. Simple as these two requirements may seem at first, what is concealed is a great web of complexity in which the problem of incompetence is entwined.

At this point I will merely point out what these issues are, withholding an attempt to resolve or reconcile them until after a discussion of incompetency.

1. Information disclosure. Patients must be provided with all information material to making a decision whether to undergo or forego treatment. This information must be provided by the physician or investigator or by someone to whom this task has been delegated, though the responsibility for seeing that it is properly done remains that of the physician/investigator. Patients need not be given information that they already know or which they can reasonably be assumed to know either by virtue of their own experience or by virtue of the fact that the information is common knowledge. How the "materiality" of particular information to making a decision is to be determined is a matter

of hot dispute. The jurisdictions are about evenly divided between two differing views, with some holding that the doctor is obligated to disclose that information which a reasonable patient would find material to making a decision, and others holding that materiality is to be determined by reference to prevailing medical custom--that is, what a reasonable doctor would tell a patient. Among the kinds of things that the doctor must tell the patient are the material risks of treatment, the anticipated benefits, and alternative kinds of treatments.

2. Consent. Whereas the problems associated with the requirement of information disclosure are largely of a practical nature, the issues associated with the "consent" requirement are primarily at a conceptual level. About the only thing that is clear about consent, is that the patient must give the doctor permission to perform the procedure, but even that is subject to some qualification.[6] The case law is extremely unclear--and the two dozen recently enacted informed consent statutes do not clarify the matter--as to whether anything more than the patient's mere permission is required.[7] What could be required, in addition, is permission based upon understanding of the information that was disclosed: that is, understanding of the nature and consequences of the proposed medical procedures.[8] What could also be required is that the doctor make reasonable efforts to determine whether the patient understands, and if the patient does not, further to make reasonable efforts to attempt to get the patient to understand. If in the final analysis, the patient does not understand the information, it is unclear whether

or not the permission he gives provides the doctor with authority to perform the procedure, or even whether the patient's refusal is binding on the doctor.

If the patient does not understand the information, it is arguable that he is "incompetent," but the courts have not clearly spelled out the relationship, if any, between lack of understanding of the disclosed information and incompetency, though I will endeavor to do so shortly.

The foregoing discussion of informed consent is based upon the common-law requirements which have developed in malpractice cases brought against doctors by patients who have been injured by therapeutic or diagnostic procedures of a non-research nature. Although we can say with a high degree of certainty that these requirements are also applicable to research procedures, there are few reported cases involving research procedures.[9]

Whatever uncertainty there might be about the applicability of the common-law informed consent requirements to research procedures--and I suggest that there ought to be none--should be dispelled by the informed consent requirement mandated by DHHS regulations, which, however, are limited in their applicability to research supported by DHHS grant or contract.[10] Informed consent is defined as

> the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

> (1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
>
> (2) A description of any attendant discomforts and risks reasonably to be expected;
>
> (3) A description of any benefits reasonably to be expected;
>
> (4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
>
> (5) An offer to answer any inquiries concerning the procedures;
>
> (6) An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject; and
>
> (7) With respect to biomedical or behavioral research which may result in physical injury, an explanation as to whether compensation and medical treatment is available if physicial injury occurs and, if so, what it consists of or where further information may be obtained . . . . [11]

Although there are some concrete differences between the common-law and regulatory requirements for informed consent, there are no conceptual differences. Both require that (1) relevant information be provided the patient/subject, (2) that consent be obtained, (3) that the patient/subject be so situated as to be able to render a voluntary decision, and (4) that the patient/subject be competent. Although there is no explicit requirement in the regulations that subjects be competent this requirement, is implicit in the statement that informed consent must be obtained from the individual or his legally authorized representative.[12]

MODELS OF INFORMED CONSENT: DIFFERING NOTIONS OF WHAT INCOMPETENCY IS

There is considerable haziness as to just what role competency plays in informed consent and thus in the implementation of the individual's right of decisional autonomy. This haziness arises for at least two reasons: (1) confusion over the conceptualization of incompetency, that is confusion over the relationship between incompetency and other aspects of informed consent; and (2) confusion over what incompetency means--that is, over the tests of incompetency. A third reason--to complicate matters even more--is that there is some overlap between these two foregoing areas of confusion!

(1) Confusion over the relationship between incompetency and other aspects of informed consent. Statements abound in the judicial cases to the effect that only a competent individual may render consent for his own medical treatment. Thus, although the informed consent requirement obligates the doctor to make disclosure and obtain consent, these duties are suspended if the patient is incompetent. Thus, although the informed consent requirement obligates the doctor to make disclosure and obtain consent, these duties are suspended if the patient is incompetent. The Restatement of Torts puts it this way: "To be effective, consent must be . . . by one who has the capacity to consent . . . ."[13] To take the most extreme example of incompetency, if a patient is unconscious, the doctor obviously need not make dis-

closure nor attempt to obtain the patient's consent. These duties are also suspended in less extreme situations such as where the patient is highly intoxicated.[14]

In this view, incompetency is a condition, which if satisfied, calls into question the doctor's obligation to make disclosure and obtain consent. I will refer to this as "threshold incompetency," for if there is clear-cut evidence of incompetency at the threshold, the physician need not bother to attempt to inform the patient and obtain his consent to treatment. This of course does not mean that the physician is then free to render any treatment that may be necessary. Rather, in all cases except the most exigent,[15] the physician must obtain informed consent from the patient's proxy, or, in the language of the federal regulations, the patients "legally authorized representative.[16] Where there is less clear evidence of incompetency--such as where a patient is mentally retarded but not profoundly so--this should serve to alert the physician/investigator that the presumption of competency which ordinarily prevails--that is, the presumption that the patient is entitled to make his own medical decisions--might not be operational in this particular case.

If the patient does not fail the test of threshold incompetency, the informed consent requirement obligates the doctor to make disclosure to the patient. If informed consent is viewed--as it should be--as something more than a simple stimulus-response model involving the input of information by the doctor into the patient and the spewing forth of a consent or refusal by the patient, the doctor will undoubtedly engage in a conversation with the patient. This conversation will involve, as most conversations do, a give-and-take of information, with the doctor telling the patient some things, the patient responding both verbally and behaviorally with indications of comprehension or confusion, with the patient occasionally asking questions of the doctor, and the doctor probably asking questions of the patient.

In the course of this conversation, the doctor may begin to suspect that the patient is incompetent. This suspicion may encourage the doctor to probe more deeply to determine whether the patient understands what the doctor has disclosed. This probing may be accomplished by direct and indirect verbal questioning, or it may be done more subtly and indirectly. As long as the doctor maintains an interrogative posture toward the patient--that is, so long as he or she is on the look-out for whether the patient understands--the doctor is likely to obtain a feeling for the extent of the patient's comprehension. Thus, in addition to being thought of as a precondition to the doctor's duty to disclose information and obtain consent, incompetency can also be thought of as arising after information has been disclosed, and usually in the process of obtaining the patient's consent. I will refer to this concept of incompetency as "process incompetency."

Both sorts of incompetency determinations are routinely made by doctors. The determination of threshold incompetency involves a general "sizing up" of the patient by the doctor. This may occur totally unconsciously, and usually will when the patient is clearly not incompetent. However, in other situations gross features of the patient such as obvious alcohol or drug intoxication, obvious hallucinations or manifest delusions, serious mental retardation, or severe sensory disorders such as blindness or deafness will alert the doctor to the possibility, if not likelihood, that the patient is incompetent. The stronger the probability of incompetency, the less likely the doctor will even attempt to obtain informed consent from the patient.

If the patient's incompetency either at the threshold or in the process of disclosure is apparent, the patient's decision about treatment (if any is expressed) need not be honored, and the decision as to whether and how the patient is to be treated may be made without the patient's further participation. Indeed, a doctor who renders the treatment on the basis of the permission of an incompetent runs the risk of liability for battery. Similarly, the doctor who declines to treat on the basis of the refusal of an incompetent patient runs the risk of liability for breach of his fiduciary duty to the patient.[17]

I have attempted to sketch out three different ways in which incompetency can be conceptualized: threshold incompetency, process incompetency, and a combination of the two. But regardless of how incompetency is viewed as relating to the larger process of medical decision-making we can delay no longer a discussion of what incompetency "is."

(2) Confusion over what incompetency means: "tests" of incompetency. Incompetency may be defined either in status or functional terms. That is, certain persons may be disqualified from exercising their right of decisional autonomy either on the

basis of some status they occupy, or because they lack the capacity to perform some function.

a. Status tests of incompetency. This method of determining incompetency focuses on certain qualities of the person whose competency is in question as a person, rather than as a patient, that is, outside the medical decision-making context rather than within it. This test functions by comparing the person in question with a hypothetical average person. To the extent that there is a gross deviation between the two, the person in question is said to be incompetent. These include (1) permanent conditions such as severe mental retardation, (2) temporary conditions such as intoxication, or (3) transitory or subjective characteristics of the person such as physical appearance, peculiar behavior, or symptoms of psychosis. To some extent, these tests employ functional criteria, but not ones specifically relevant to medical decision-making. Indeed, most of the status labels denote functional disabilities of some sort, but instead of measuring functional criteria for medical decision-making directly, status tests measure them indirectly by focusing on features from which medical decision-mkaing capacity may be inferred. That is, we conclude without actually measuring that an individual occupying a given factual[18] status is incapable of participating in the medical decision-making process.

b. Functional tests of incompetency. In general, a functional test of incompetency seeks to answer the question "Is this patient able to participate in the medical decision-making process?" A negative answer to this question results in a finding that the patient is "incompetent," thus depriving the patient of decisional autonomy. In fact, this very question might be taken as a "test" of incompetency, except that it is so general as to be all but useless in particular cases. Rather, it is necessary to specify particular features of the medical decision-making process which, if lacking, would render the individual unable to participate in the process to the extent required by law. Functional tests of incompetency are unconcerned with the patient's status _qua_ status. Thus if a patient is, for example, "mentally ill," the presumption of competency is not automatically overcome. However, depending upon which functional test is utilized to determine incompetency, the effects which the mental illness has on the patient's cognitive abilities may be taken into account, and may, but need not necessarily, lead to the conclusion that the patient is incompetent.

(1) _Absence of decision_. One functional test of incompetency focuses on the absence or presence of a decision by the patient. A patient who chooses one treatment rather than another, or no treatment at all, is deemed competent. If the patient makes a choice, there is no further scrutiny of the manner in which he makes the choice, the reasons given for the decision, or the nature of the decision itself. By contrast, a patient who makes no choice when presented with the opportunity to do so is deemed incompetent. The mere failure to manifest a choice is determinative of incompetency. The person who is mute when asked to make a choice may well be incapable of receiving or communicating information, or such a person may be psychotic. If that is

the case, this functional test of incompetency may well overlap with the status tests of incompetency. This test of incompetency allows the presumption of decisional autonomy to remain undisturbed unless there is extremely strong evidence of incompetency. Or to put it slightly differently, this test establishes an extremely high level of dysfunctioning as the test of incompetency.

(2) Nature of decision-making process. Other tests of incompetency focus on the nature of the decision-making process employed by the patient. After the patient is provided with the information mandated by the informed consent requirement, the doctor makes inquiry into the manner in which the patient makes a decision concerning treatment. Certain ways of making decisions could be viewed as acceptable, and others as unacceptable. A patient who employs an unacceptable means of making a decision is labelled incompetent.

These approaches to the determination of incompetency are grounded in the view that if a patient is able to make a decision but is unable to make it in the preferred manner, then the decision is something less of a decision and less deserves to be honored. The problem with this approach is that it is fundamentally inconsistent with the broad legal and ethical basis of the informed consent doctrine which permits patients to make decisions for their own idiosyncratic reasons if they so choose. Put another way, the doctor's duty of disclosure is intended to enable patients to make their decisions on the basis of that information, but not to require that they do so.

(a) Failure to articulate reasons in support of the decision. A patient who is able to manifest a choice, and thus pass the "absence of decision" test, may still not be able to articulate reasons in support of that choice. Under this view, such a patient is deemed incompetent. This test would find more persons incompetent than the "absence of decision" test.

(b) Failure to articulate rational reasons in support of the decision. A person who could articulate a basis for his decision might still not be able to articulate rational reasons for that decision. That is, a patient might be deemed incompetent if the basis for the decision does not reflect both the information provided by the physician or other articulable reality-based information. This information need not necessarily be objectively factual; indeed the subjective value preferences of the particular patient such as his tolerance for pain and suffering, and his business, social, and personal obligations which might be compromised by treatment would all be legitimate reasons for a decision for or against treatment. By contrast, non-objectively verifiable reasons--such as hallucinations or delusions--could be deemed non-rational grounds for decision which would deprive the patient of his decisional autonomy. Needless to say, this test of incompetency is far more subjective than either of the foregoing tests.

(c) Failure to employ a utilitarian calculus. An even stiffer test of incompetency--that is one which would deprive a far greater proportion of persons of their decisional autonomy--focuses on the patient's use of a utilitarian calculus to arrive at a decision. This test is suggested in the first instance by the informed consent requirement itself which, because it requires the doctor to disclose risks and benefits to the patient, could be construed as suggesting that the patient should weigh risks against benefits. A patient could easily articulate rational reasons in support of the decision that he makes yet fail to weigh the benefits of a particular course of action against the risks. This test is even more subjective than the foregoing one because it not only requires the tester of incompetency to determine the factual veracity of a particular reason, but requires the evaluation of the weight given to particular benefits and risks, which is an inherently subjective enterprise.

(3) Nature of decision. Incompetency could also be tested by reference to the outcome of the decision-making process, rather than by reference to the nature of the process. For instance, the failure to make a decision that is in accordance with some externally verifiable standard might be deemed to render the patient incompetent. Examples of such standards are (a) what a reasonable person would decide under the same circumstances, or (b) what the physician has recommended. For example, any patient who chooses no treatment over treatment, or a risky treatment over a less risky one could be deemed incompetent if a hypothetical "reasonable person" would not make such a choice. Or a patient whose decision is different from the doctor's recommendation could be deemed incompetent. Such tests verge on undermining, if they do not actually do so, the patient's decisional autonomy by

honoring its exercise only where it is congruent with societal standards.

(4) Lack of understanding of "informed-consent" information. Another functional approach to incompetency involves determining whether or not the patient understands the information relevant to rendering an informed consent. There are two varients on this test:

(a) Actual understanding. The most straightforward way of applying this test is for the doctor (or other person) who has made disclosure to the patient of the requisite information to determine whether or not the patient understands it. A patient who does not understand the information is deemed incompetent, and deprived of his decisional autonomy. No inquiry need be made into how the patient uses the information or even whether he uses it; nor need there be any scrutiny of the reasons that the patient has for making a decision, nor of the nature of the decision itself. Rather, if the patient does not understand the information, he is deemed incompetent and deprived of his right of decisional autonomy.

A serious problem can occur in the administration of such a test from the fact that "understanding" is rarely if ever a simple yes-or-no matter. And further, since there is not merely one discrete bit of information that is disclosed but a range of information about risks, benefits, alternatives, and the nature of the procedure, as well as varying magnitudes and probabilities of risk and benefit, the measurement of understanding is a highly complex undertaking, to say nothing of establishing the level of adequacy of understanding.

This test best illustrates the conceptual overlap between incompetency and the "consent" element of informed consent. If consent means more than mere permission, as I earlier suggested that it does, and involves the giving of permission with an understanding of the nature and/or consequences of the touching that is to occur, then a requirement of competency is redundant. That is, when the courts state that a doctor may render treatment only on the basis of the informed consent of a competent person, they are either engaging in a redundancy or they are requiring something else in addition to understanding of the disclosed information.

(b) Ability to understand (potential understanding). Instead of measuring directly the patient's understanding of the information given by the directly, the patient's understanding of this information could be determined inferentially. The patient might be administered a formal intelligence test, for example. Or the patient's ability to understand informed-consent information might be inferred from informal conversation with the patient. No matter what the basis of the inference, this variant encounters the same problems as the test based on actual understanding. Moreover, a further problem is introduced by the fact that the logical inference that is made may not be valid. This variant is similar to status tests of incompetency because it seeks to determine a patient's competency without directly measuring it, but instead by inferring it from something else.

Any test which seeks to determine "understanding" is particularly susceptible to the same problem that occurs with the "rational reasons" or "nature of decision-making" tests. In attempting to gauge understanding, the values of the tester play an insidious, and probably unavoidable, role. Not only does the tester's view of what constitutes understanding affect the determination of incompetency, but the initial selection of the information that the patient is to be tested on reflects the importance that the tester attaches to what information should be understood in order to be viewed as competent. Thus the personal identity and professional allegiance of the tester play a highly influential role in determining whether the patient is incompetent.

TESTS OF INCOMPETENCY AND RESEARCH SUBJECTS

Returning to our original concern--"What would it mean to be competent enough or refuse participation in research?"--several things are now clear:

This question _is_ worth asking and answering. This is because in order to authorize one's own participation as a research subject, one must be able to render informed consent. And, in order to render informed consent, one must be "competent"--or, as I prefer to put it, one must not be incompetent.

There is a difficulty in specifying what it means to be competent to make a decision to participate in research because it is uncertain how incompetency is to be measured. I have described two different approaches to the determination of incompetency--status and functional tests--and there are several variants on each of these general approaches. No authoritative law-making body has ever, to the best of my knowledge, authoritatively specified how incompetency is to be determined. There are some dicta in cases, but since the question has never been squarely presented for consideration, there is no authoritative holding on the matter as yet.

Because of the legal "presumption of competency," that is, that all persons are presumed competent until an authoritative determination is made to the contrary--and it is not at all clear who is to make such a determination--we should approach our question in a slightly different way. Instead of asking "What would it mean to be competent enough to consent or refuse participation in research?" we should ask "What would it mean to be incompetent enough not to be able to participate in research?" Although the grammatical difference between the two questions is slight, the legal difference is much greater. As a result of the legal presumption of competency, all persons are presumed competent to consent to or refuse to participate in research. Their decisional autonomy may be stripped away only on a showing of incompetency. Investigators need not be concerned at the outset whether a person is competent to be a subject; the investigator is entitled to assume that the person is. Rather, investigators need only be alert to evidence that the subject is incompetent, at which point participation should either be denied or discontinued, depending on whether there is threshold or process incompetency.

Now I must finally stop begging the question. Suppose we suspect incompetency. How do we assure ourselves that the subject is or is not incompetent? Given the multitude of tests proposed, which one should be applied?

I recommend a conjunctive approach utilizing both threshold and process tests of incompetency. If the patient suffers from any serious physical or mental infirmities, incompetency should be suspected and further determinations made. If the patient is not clearly incompetent at the threshold, disclosure should be made to the potential subject of the legally mandated information--that is, that information required both under federal regulations and under applicable state law, though ordinarily this will be the same information, and a process-test of incompetency should then be applied.

Which one? The lack of clarity in law as to how incompetency is to be determined--that is, which test of incompetency is to be applied--results from two problems, one ideological, the other pragmatic. The ideological problem has its origins in the fact that there is no clear-cut societal consensus as to how competing values in the medical decision-making process are to be reconciled.[19] Therefore, because of the lack of consensus, it is not possible to be sure of which test to select. The pragmatic problems arise from the tremendous difficulty in applying abstract tests--assuming we first know which one to use--to concrete cases with any assurance of validity and reliability.

The "absence-of-decision" test of incompetency most honors individual autonomy,[20] since it permits the subject to govern his own destiny regardless of the manner in which he makes a decision, and regardless of what the reasons for the decision may be. However, this test places great strains on society's interest in health and in assuring the integrity of the health professions, since its application may result in the denial of highly beneficial treatment to very sick people.

At the other extreme is the "nature-of-decision" test. Because it honors only those decisions of a subject which correspond in nature with those established by an external standard, it thoroughly undermines the value of individual autonomy, by disproportionately favoring society's interest in health and in the professions.

The other tests--"lack of understanding," and "failure to articulate reasons"--fall somewhere between these two extremes and thus do not unduly favor either constellation of values to the exclusion of the others. Each has aspects to commend itself, as well as difficulties militating against its use.

I recommend starting with the "actual-understanding" test. This test commends itself above all others because it is implicit in the idea of "consent." Problems of administration of this test are not insubstantial, but a common-sense approach in which the investigator has a conversation with the prospective subject about the information relevant to the research is likely to tip-off the investigator to any misapprehensions that the subject may harbor.

More specifically, the investigator should be focusing on the patient's understanding of those things which the common-law and regulatory definitions[21] of informed consent require disclosure of:

(a) The fact of being a research subject. The first requirement of the regulatory definition of informed consent is that the subject be informed of "the procedures to be followed, and their purposes, including identification of any procedures which are experimental." Another requirement is that the subject is to be provided with a "description of any benefits reasonably to be expected." Although the regulations do not explicitly state this, the language of these two provisions can be fairly read to require that the subject be told that he is a research subject. This is probably the most important aspect of informed consent to research, and thus the subject should understand that he is a research subject. In the case of non-beneficial[22] research, the subject must be told and understand that the primary purpose of the procedures to which he will be subjected are to acquire knowledge and not to benefit him personally and directly. Where the research is beneficial, the subject must be told that the purpose of the procedures is not solely for his benefit, but in part for his benefit and in part for the acquisition of knowledge more generally.

These are fairly sophisticated concepts. I have seen intelligent law students experience some difficulty in understanding the difference between therapy and research. It is no wonder that patients, and especially menally ill patients, have difficulty with this concept.

(b) Alternatives to participation. Both the common law and the federal regulations require that subjects be informed of "any appropriate alternative procedures that might be advantageous . . . ." Thus the subject ought to understand, in the case of beneficial research, that there are other things that the doctor could do to provide relief from illness or injury. Where the alternatives are not themselves experimental, the subject should understand that fact, and vice-versa.

(c) Right to terminate participation. The subject should be told and should understand that consent to participate is revocable at any point, and that there will be no collateral loss of privileges as a consequence of withdrawal. This is far easier to state in the abstract than to explain concretely to a subject, and it is likely that it is far more difficult for the subject to understand than it is even to explain. Clearly, withdrawal from a research protocol may have some legitimate untoward consequences for the subject, such as the fact that he may now have to pay for care that was previously being financed by research grant funds. Thus, to boldly tell the patient, as the federal regulations require, that he "is free . . . to discontinue participation in the project or activity at any time without prejudice . . ." is just not so. Therefore, determining whether or not the subject "understands" the right to withdraw is extremely difficult to determine because it is not at all clear what the extent of the right is.

(d) Right not to participate. Neither the federal regulations nor the case law explicitly requires the investigator to inform potential subjects of their right not to be research subjects. However, this right is implicit in and fundamental to the notion of informed consent. Thus, potential subjects ought to understand that they are free not to enter the research protocol, and of course they should be told this. I suppose that they should also be told that they are free not to be subjects "without prejudice," but this is even hazier here than with respect to the right to withdraw.

Take for example the patient who is admitted to a clinical research ward in a psychiatric hospital. If the patient refuses to participate in a given research protocol or in any protocol, there is no reason for him to be hospitalized on a research ward, and in some cases there may be no reason for him to be hospitalized at all. In order to obtain the patient's informed consent, the patient has to be told about alternatives. Alternatives to being on the research ward may include being hospitalized elsewhere in the hospital, being treated as an outpatient, being sent to another hospital, or not being treated at all. If the patient is admitted to a research ward, and then refuses to participate in a research protocol (or withdraws from one), one of these alternatives will come into play. And might they not constitute "prejudice" to the subject? Thus to comply with one requirement of informed consent is to deny fulfillment of another.

(e) Other aspects of understanding. Similarly, the subject should understand all of the other information that he is given--about risks and discomforts, having questions answered, and the (non)availability of compensation for research-induced injuries.

The foregoing is what should be done if an "actual-understanding" test of incompetency is to be applied.

If taken seriously, it establishes a very high standard of competency, which may disqualify potentially large numbers of persons from exercising decisional autonomy. At the same time, however, since an incompetent person cannot be made a research subject without the consent of his legally authorized representative, it is possible that the added factor of third-party review of the decision to be admitted into a research protocol will afford added protection to subjects against unreasonable risk-taking.

It is possible, however, that a patient may "pass" an "actual-understanding" test and yet leave a feeling in the investigator that he does not really understand what the research is all about. This may be the case because the subject is unable to articulate any reasons or is unable to articulate rational reasons in support of his decision, because the subject does not weigh risks against benefits in making his decision, or because the subject declines to participate in beneficial research when there are no alternative treatments (i.e., because of the nature of the subject's decision). That is, the patient may pass one test of incompetency but fail another.

SOME THOUGHTS ON WHAT "UNDERSTANDING" IS AND IS NOT

The foregoing discussion suggests--and I believe that we would all agree from our experience--that one can understand discrete aspects of a problem without having a complete grasp of the whole problem; that is, the whole may be greater than the sum of the parts.

I believe that a subject could "pass" an understanding test of incompetency, yet leave the investigator dissatisfied that he really understood what the research was all about, even at a layman's level. This statement assumes that we are able to determine what "passing" an understanding test would involve; I am not sure that we can. At this point, I will not actually try to do so, but merely content myself with specifying some of the issues that will arise in such an undertaking.

First, mere parroting of information does not constitute understanding. As I have noted elsewhere, too many empirical studies of informed consent conclude that patients do not understand, when what they really mean is that with the passage of time, patients tend to forget what they were told. However, some minimal amount of retention of information is a prerequisite to genuine understanding, whatever it may be. Thus, while lack of short-term recall is evidence of a lack of genuine understanding, the converse is not so: the ability to recall and repeat what one has been told should not be mistaken for genuine understanding.

At the other end of the spectrum, neither is genuine understanding in this context to be equated with that level of understanding which the investigator himself or other scientifically trained persons might have. Something far less than that level of understanding will suffice for a subject to be considered not incompetent to give informed consent to participate in research.

What degree of understanding, then, is sufficient? This cannot be defined with precision, and even a description is difficult. Courts have used the term "appreciate" in their discussions of consent and competency. That is, the subject should not merely be able to repeat information that he has been given, but should appreciate its significance in the context. The context that is relevant may include the facts that the individual is a research subject; that he is a patient; that he is in a hospital; that the person speaking with him is a physician; that the procedures are or are not being performed in whole or in part for the acquisition of knowledge. In short, the subject must be able to integrate the relevant information into a meaningful whole.[23]

CONCLUSION

The enterprise of determining what it means to be competent enough to consent to or refuse participation in research is fraught with perils on both ends. At one extreme, we run the risk of setting the level of competency so high that few will attain it, and as a result deny the fundamental right of decisional autonomy to all but a few. At the other extreme, we take the chance of setting the level of competency so low that great numbers of persons will subject themselves to the risks of participating in beneficial research or to the risks of not participating in beneficial research which they do not genuinely desire to take.

The risks are not solely to the individual. There are risks to society from setting the level of competence too high or too low. By setting it too high, we may assure that valuable research is not undertaken, with the consequent loss of potential social benefit. By setting it too low, we run the risk that many people who need treatment may not get it or that people who do not, will. Either type of error has social costs as well as individual costs.

References

1. 45 C. F. R. Part 46. [EDITOR'S NOTE: All references to DHHS regulations are cited from OLD regulations. NEW DHHS regulations were promulgated on January 26, 1981, and will be in effect from July 27, 1981. See Appendix: "DHHS Regulations and Psychiatric Research: New Guidelines for Informed Consent".]

2. Schloendorff v. Soc'y of N.Y. Hosp.

3. I will not be referring to those who are incompetent on the basis of their age when I speak of competence or incompetence to exercise decisional autonomy, though we should not lose sight of the existence of this category. I make the distinction in part becsuse the law does, in part because the values and issues at stake are somewhat different, and because the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research and the Department of Health and Human Services treat the problems separately. But fundamentally, we should not lose sight of the common link between these two groups -- children and mental incompetents -- namely that they are both deprived of their right medical decisional autonomy.

4. The Nuremberg Code is reprinted in full in G. Annas, L. L. Glantz, & B. Katz, INFORMED CONSENT TO HUMAN EXPERIMENTATION (1977), 279-280.

5. The Declaration of Helsinki is also reprinted in full in Annas, et. al., op. cit. at 281-283.

6. E.G.. waiver, emergency; silence v. affirmative permission; i.e., implied consent.

7. I use the term "permission" in the same sense that the proposed regulations governing research with institutionalized mentally disabled persons use the term "assent":

> "Assent" means a prospective subject's affirmative agreement to participate in research ... given following an explanation [of the elements of informed consent]. 43 Federal Register, 53:950, 954-955 (Nov. 17, 1978, proposed 46.503 (i).

8. See 56 Neb. at 12123.

9. Murphy v. Devito, No. 79 CO 1320 (Cir. Ct. Cook City, Ill. 1979): Kaimowitz; Bailey v. Lally, No. K-1102 (D. Med. July 21, 1979); See also, "Prisoner Loses Suit Claiming Coercion to Participate in Research" 1(5) IRB: A Review of Human Subjects Research, 1979.

10. 45 C. F. R. at 46.101 (a), 46.102 (a).

11. 45 C. F. R. at 46.103 (c)

12. This is also elaborated upon in the proposed regulations governing research with institutionalized mentally disabled subjects. See U.S. Department of Health, Education, and Welfare, Protection of Human Subjects: Proposed Regulations on Research Involving Those Institutionalized as Mentally Disabled. 43 Federal Register, 53:950 passim. November 27, 1978.

13. Restatement Second of Torts 1 892A (2) (2) 1979.

14. A problem with suspending the duty to disclose at the threshhold where the patient is thought to be competent for any reason other than unconsciousness is that it is always possible, though admittedly unlikely, that disclosure could be made to such a person, that it could be understood, and that consent could be given if the effort were actually made to obtain informed consent.

15. Where the physician wishes to render conventional therapy to an incompetent patient in an emergency, there is ordinarily no barrier to his doing so. See generally, Meisel, "The 'Exceptions to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision-Making." 1979, WIS. L. REV. 413, 434-438.

16. 45 C.F.R. at 46.103 (c). The federal regulations carefully skirt the problem of who qualifies as a "legally authorized representative", leaving the matter to be determined according to state law. The problem with this solution is that in few states is the law particularly clear on who qualifies as a legally authorized representative. In only two states, Louisiana and Utah, where there are specific statutes is the matter clear. (See generally, Meisel & Kabnick, "Informed Consent to Medical Treatment: An Analysis of Recent Legislation." 41, U. PITT. L. REV. 407, 458-66 (1980). However, in all states, a petition can be filed in a court of appropriate jurisdiction to have an individual adjudicated incompetent and a guardian appointed. Where this has already been done prior to the person's entry into a research protocol, the guardian may have the authority under state law to authorize participation as a research subject. Whether the guardian does have such authority is dependent both on the scope of the court decree adjudicating the individual incompetent, and applicable case law of which there is little or none. Alternatively, an individual may be adjudicated incompetent for the very purpose of rendering medical treatment, either in a research protocol or otherwise. If the court finds the person incompetent and appoints a guardian, it will then be for the specific purpose of deciding whether or not to permit the individual to be a research subject.

In both situations--adjudication of incompetency before the issue of research arises, and adjudication of incompetency in contemplation of medical research--the court will have to determine whether the individual is incompetent, and in so doing will have to apply some test of incompetency. Thus the matter of how incompetency is to be determined arises whether the determination is made by a judicial or medical authority.

17. Whether the process is terminated at the threshold, that is, before it even begins, or whether it is terminated at some point in the course of making disclosure and obtaining consent, the label of "incompetency" is still applied to the patient. As a result of this labelling, certain things should ensure as a matter of law. First, no conventional treatment should be rendered, unless there are extremely exigent circumstances. Instead, a proxy decision-maker must be obtained. As a matter of practice--a practice that is so deeply embedded that it may as well be deemed a matter of law, if in truth it is not--close family members are usually consulted and informed consent obtained from them.

This practice has begun to be called into question in cases involving the rendition of extraordinary forms of medical care, but as of yet there is no definitive law judging the propriety of this practice in routine situations.

In some cases, there are no family members to whom the doctor can turn to obtain informed consent. (Some states have statutes permitting the hospital director to authorize medical treatment for involvuntarily committed mental patients). In other situations, the family members may be in disagreement as to what should be done or may, after being informed, refuse rather than consent to treatment for the patient in question. In such cases, the doctor is faced with the choice of whether or not to institute judicial proceedings to have the patient declared incompetent as a matter of law, and to have a guardian appointed to authorize the recommended medical care.

Whether or not a doctor is obligated to institute proceedings to obtain a judicial declaration of incompetency under these circumstances, or whether he may merely decline to render the recommended treatment on the ground that the patient has not "consented" because incompetent to do so has never, to my knowledge, been explicitly ruled upon. But see, Steele v. Woods, 327 S.W.2d 187, 198 (Mo. 1959) (dictum). I would venture, however, that since the nature of the doctor-patient relationship has repeatedly been said by courts to be a "fiduciary one" conferring upon the doctor the utmost obligation of fair dealing with and protection of the patient, that any harm that accrued to a patient who was not treated because he could not competently consent and because the doctor failed to obtain a judicial ruling upon the patient's competency might well render the doctor liable.

A full discussion of the problems of proxy decision-making are beyond the bounds of the present topic. Suffice it to say that despite some legislative forays into this area in recent years, the law is extremely unclear as to what should be done when a patient is incompetent.

18. As I mentioned earlier, a person is incompetent if he occupies a particular legal status such as a child or a person adjudicated incompetent by a court. In these cases, the person is probably also incompetent to make medical decisions, but in the context of the current discussion, I am not referring to these groups when I use the concept of "status-incompetency".

19. For a more detailed discussion of the values, see Meisel, op. cit. at ref. 15 supra.

20. See Roth,, Meisel, & Lidz, "Tests of Competency to Consent to Treatment". 1977, Am. J. Psychiat.

21. See 45 C.F.R. at 46.103 (c).

22. "Non-beneficial" research is a term of art -- synonomous with "non-therapeutic" research -- used to denote a particular research procedure which is not intended to confer direct, therapeutic benefit on the subject, but is intended only to acquire knowledge. Non-beneficial research may, in fact, confer benefit on the subject; the distinction between it and beneficial research has to do with the investigator's intent, not with the reasonably foreseeable consequence.

23. I do not contend that he must be able to view the information in the same way that the investigator does; nor that he be able to understand the view of the information that the investigator holds though rejecting it himself. For example, the investigator may tell the patient that the purpose of a procedure is to relieve his depression. The subject may be able to explain that the investigator believes that the procedure is intended to relieve depression. But the subject may himself believe that the procedure is intended to kill him. If this is the case, I do not believe that the subject can be said to be competent.

Competency to Consent to Research: A Psychiatric Overview

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The issue of competence to consent to therapeutic and experimental procedures, once a neglected topic of interest only to a small group of legal and medical academics, has recently been propelled into the forefront of debate about medical and experimental ethics. Many of the same factors that have led to profound interest in informed consent--a growing distrust of professionals in general, a rising consumerist and self-help orientation, and the exposure of some startling examples of the misuse of trust by medical experimenters--have led in turn to an examination of the presumed prerequisites to effective informed consent, competence among them. Despite its recent prominence, however, the issue of competence (sometimes referred to as capacity) to consent to research is of relatively recent derivation and awaits generally acceptable attempts at definition. This paper will review the previous literature on the elements of competency, and outline the psychopathologic phenomena that might impair subjects' performance. Finally, the factors that might influence the choice of standards for competency and the possible implications of those choices will be discussed.

The relevance of an individual's mental capacity to the adequacy of his consent to participate in research was first formally recognized in the Nuremberg Code, the initial attempt to codify the ethical principles that should guide human experimentation. (1) The Code, elaborated in response to the revelation of Nazi atrocities committed in the name of advancing medical knowledge, deemed "absolutely essential" the "voluntary consent of the human subject," and continued: "This means that the person should have legal capacity to give consent." Along with capacity, the free power of choice and sufficient knowledge and comprehension to enable an understanding decision were singled out as the touchstones of what later came to be called the doctrine of informed consent.

Of interest in the Nuremberg formulation - which some have argued was designed exclusively to deal with non-therapeutic research - is the seemingly absolute nature of the requirement for legal capacity. There is no provision in the Code for any procedures that would permit subjects lacking in capacity to participate in research. This situation was altered with the promulgation of the Declaration of Helsinki by the World Medical Association in 1964. Now the most widely recognized code governing experiments with humans, the Declaration distinguished between "clinical research combined with professional care" (i.e., research that might lead to therapeutic gains for the subjects) and "non-therapeutic clinical research." (1) In each category, it appeared to allow the consent of a third party to be substituted for that of the incompetent subject: for clinical research combined with professional care - "If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent...In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity, the permission of the legal guardian replaces that of the patient;" for non-therapeutic clinical research - "Clinical research on a human being cannot be undertaken without his free consent...; if he is legally incompetent, the consent of the legal guardian should be procured."

At approximately the same time as the discussion that led to the Declaration of Helsinki, public attention in the United States was being drawn to the need for procedures to prevent harm to research subjects. This heightened awareness of the need for regulation was prompted by the revelation of the effects of thalidomide on fetuses in Europe, (2) the well-publicized episode of the injection of live cancer cells into unconsenting patients in a Brooklyn hospital, (3) and the recognition that few systematic means of monitoring research existed in this country. (4) As the scope of possible abuses widened, (5) the first sets of governmental guidelines controlling clinical research were issued by the Food and Drug Administration (relating to investigational use of new drugs) and, in 1966, by the U.S. Public Health Service (relating to the clinical research that it funded). (2) When, in 1971, the guidelines were codified, the participation of incompetent subjects was explicitly permitted as long as consent had been obtained from a legally-authorized proxy. (6)

The reliance on the idea of "legal" incompetency in the codes and regulations shifted from the medical to the legal professions the burden of deciding which subjects' mental incapacities precluded their participation in research. Yet, despite the cachet of legal authority that this move seemed to lend to the competency decision, the fact was that Anglo-American law had never clearly formulated the criteria to be used in measuring legal incompetency. (7) Nor was it clear whether the standard that should be utilized was one of general incompetency to conduct one's affairs or some more specific and limited measure, such as incompetency to make a contract.

The leading court case to date on the issue of human experimentation, Kaimowitz v. Department of Mental Health (8), did little to clarify matters. Ruling on whether a prisoner had the ability to give informed consent to a psychosurgical procedure that might affect his chances for release, the Kaimowitz court held that "the very nature of his incarceration diminishes the capacity to consent to psychosurgery. He is particularly vulnerable as a result of his mental condition, the deprivation stemming from involuntary confinement, and the effects of the phenomenon of 'institutionalization.'" By appearing to confuse the Nuremberg Code's requirement for freedom of choice, which the court felt was inherently deficient in a prisoner, with the question of mental capacity, Kaimowitz demonstrated the conceptual pitfalls that await those approaching the subject of competency. The implication that a potentially coercive environment renders an individual incompetent to make choices regarding his future has been widely condemned. (9,10)

Following Kaimowitz, the most significant effort to define the relationship between a subject's competency and the adequacy of his consent to research was the work of the National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research, notably in their report on research with the "institutionalized mentally infirm." (11) The Commission recommended a sliding scale of consents, varying in stringency with the degree of risk posed by the research and its potential therapeutic benefit to the subject. For minimal risk research, mere "assent" was required, constituting a lower standard for competency for that particular situation. Participation by incompetents in research posing higher degrees of risk was permitted only with a variety of types of substituted consent and supervision of the consent process. The failure of the Commission's elaborate conclusions definitively to settle the debate about the participation of subjects with impaired capacity is demonstrated both by the many objections to the Commission's reports (12) and by the failure of DHEW (now DHHS) to formally implement either the Commissions's recommendations or its own modifications of the Commission's report. (13)

Regardless of the nature of the ultimate solution to the regulatory issue, it is apparent that the problem of competency of potential subjects will continue to play an important role in its formulation. Yet, more than thirty years after the enunciation of the Nuremberg Code, the criteria required for a determination of legal incompetency remain ambiguous. Although the rules governing competency are legal ones, and as was demonstrated clearly by the Kaimowitz decision, are rooted in public policy considerations, psychiatry can contribute to the outcome of the deliberations by delineating those aspects of mental dysfunction that may impair capacity to consent.

Standards For Competency

Efforts to define standards for competency to consent have not been rare, although most such efforts have been directed towards the issue of consent to treatment rather than consent to research. The various standards that have been proposed appear generally to cluster into four groups. While the relationship among these groups requires further empirical study, our clinical experience plus the literature we have reviewed suggest that these 4 groups may be hierarchically arranged to furnish a progressively more stringent standard for assessing a subject's competency.

A - Evidencing a Choice (See Table I)

The least rigorous standard for competency (once the subject has been adequately informed about the nature of the research) is the subject's actual communication of a decision as to his participation in the proposed project. (14,15) This requirement has been phrased as demanding that the subject "manifest his consent" (18) or "express a positive interest in taking part." (17) A more behaviorally oriented indicator of this standard, one that places less emphasis on the subject's verbalizations, is the requirement that the subject has "cooperated appropriately in the early procedures involved in the study." (17)

The suggestion that the overt manifestation of a subject's choice is important for a competent decision is frequently omitted from discussions of the topic, perhaps because of its apparent tautological nature. One group of authors, for example, who propose to eliminate entirely the element of competency from the triad of informed consent, nonetheless would have a court that "finds before it a person who fails to respond to pertinent questions" deem the individual not have rendered a valid consent. (18)

Relevant psychiatric aspects - Psychiatric states that interfere with the ability to manifest a choice include mutism, as a result of catatonic stupor or severe depression; catatonic excitement; mania; profound psychotic thought disorder (e.g., psychotic word salad) that renders communication unintelligible to others; and marked ambivalence, as in schizophrenic or severe obsessive states, where the stability of a choice, assuming one can be manifested, is not evident even over a reasonably short period of time.

Testing for Competency - To the uninitiated, operationalizing the requirement that the subject evidence a choice may seem a trivial exercise; in most instances one need only ask the subject whether or not he desires to participate. There are occasions, however, in which the communication from the subject will be so ambiguous as to raise serious questions about whether or not consent has occurred. These include cases in which the subject's verbal and behavioral responses diverge: for example, when a subject declines to participate in a study requiring venipuncture, then rolls up his sleeve and holds out his arm to the experimenter.

In ambiguous cases of this type, or in cases in which the vector of the subject's choice appears evident but its constancy is uncertain, there is merit in deferring participation until the subject's choice can be ascertained more clearly, either as a result of repeated contacts or in response to a second individual eliciting the consent. Analogous suggestions have been made previously that certain types of non-experimental procedures that involve substantial risk for the subject--such as sterilization--be subject to a mandatory waiting period after the initial solicitation of consent, in part to assure the constancy of the response. (19)

B - Factual Understanding of the Issues (See Table II)

The subject's understanding of the issues relevant to participation is the single factor that has been most widely accepted as a standard for competency. A typical formulation requires that the subject have "the cognitive capacity to consider the relevant issues." Those areas that have been considered to be of crucial relevance for the subject to understand include: "the nature of the procedure, its risks, and other relevant information," (8) "the nature and likelihood of success of the proposed treatment and...of its risks and side-effects," (15) "the available options, their advantages and disadvantages," (19) "the knowledge that he has a choice to make," (20) "who he is, where he is, what he is reading and what he is doing in signing the paper," (21) and "the consequences of participation or non-participation." (22) At an extreme, the recently promulgated DHHS regulations for obtaining informed consent require that up to fourteen separate items, including such things as the availability of compensation for injuries, be disclosed to, and presumably understood by, the potential subject. (13) The rigor of the requirement of understanding obviously increases with the amount and complexity of material that is required to be understood. Some writers make understanding the sine qua non of their standard of competency, (23) and it has long been the primary element of legal tests of contractual and testamentary capacity. (7)

"Factual understanding" actually encompasses two different standards: one can require, as many writers do, that the subject have the "ability to understand," or more strictly, one can insist that the subject manifest "actual understanding" of the material. (14) A modified and limited "ability to understand" standard appears to be coupled with an "evidencing of choice" standard to establish the standard for "assent" to minimal risk research in the recommendations of the National Commission for the Protection of Human Subjects of Biomedical Research, (11) a standard that approximates the level existing in the days prior to the advent of the law of informed consent.

Relevant psychiatric aspects - The elements of an individual's mental functioning that seem important to his ability to display a factual understanding of the issues include: intelligence, (24) of which IQ may be one measure and adaptive capacity to the tasks of everyday life another; language skills (24); attention (25); orientation (17); recall; and recent memory. (25,17) Intelligence can be impaired by mental retardation or a variety of organic states; adaptive capacity is further susceptible to limitation by chronic psychiatric illness and probably by the effects of institutionalization. The other factors are all likewise capable of being impaired by long-standing brain damage or acute toxic states. Attention and orientation may also suffer during acute psychotic episodes, and there is some evidence to suggest that memory may be impaired in chronic schizophrenia. (26)

Testing for competency - Means of demonstrating a subject's actual understanding of issues related to his decision include, in increasing order of difficulty, asking him to repeat the information provided, asking him to paraphrase it in his own words, and requiring that he display an ability to put some or all of the information to practical use. One difficulty in testing understanding of the consequences of a decision (often conceptualized as the risks and benefits) is the possibility of divergence between what the investigator perceives as a benefit or a risk and the subject's view of the matter. (27) Consequences of participation such as prolonged hospitalization, often thought of as a disadvantage, might seem quite desirable to a socially isolated or otherwise impoverished subject.

C - Rational Manipulation of Information (See Table III)

One step beyond measuring factual understanding is determining how the information that the subject assimilates is utilized in the decision-making process. The rubrics by which this standard is discussed include: judgment, (25) rationality, (24) rational weighing of risks and benefits, reality testing, (25) and decision-making capacity. Legal rules concerning contractual and testimonial capacity have traditionally recognized at least one defect of rationality - the presence of "insane delusions" - as grounds for invalidating an individual's acts. (7)

Relevant psychiatric aspects - In addition to delusions, which are acknowledged by a number of writers as potentially significant factors affecting competency, (28,15) other symptoms that may have a similar effect include: hallucinations, loosening of associations or other severe thought disorder, and severe or extreme degrees of phobia, panic, (20) anxiety, (25) euphoria, (20) depression, (20) anger, (20) agitation, and obsessive preoccupation. The existence of a pathologic relationship (i.e., one marked by excessive dependency, (20,25) passivity, (25) or unwarranted trust (25)) with the party seeking consent, or with someone who may be affected by the consent, has been suggested as a factor that could also contribute to impaired rationality. This condition, however, seems to be related more to the issue of the voluntariness of the decision, to the appreciation of alternatives, or to the knowledge that a decision needs to be made.

Testing for competency - Rationality is frequently tested in the mental status examination by the standard questions that elicit hallucinatory and delusional material (e.g., Schneiderian signs) and by the use of vignettes that pose a problem to which the patient is asked to respond. A less structured test suggested by Cole is whether the potential subject can carry on an ordinary conversation in such a way as to indicate that he can understand questions and answer in a logical and reasonable manner. (17) In troublesome cases, it may be necessary to inquire about or to observe the rationality of the subject's decision-making outside of the formal psychiatric examination. Data from family or friends may establish that the seeming rationality displayed in the examining room is abandoned by the subject when he is confronted with real demands for action.

The subjective nature of any assessment of rationality has frequently been pointed to as a major obstacle to the successful employment of such a test. (23) But an even greater problem may lie in the consensus of most experts today that an impairment of rationality does not necessarily affect global decision-making ability; that is, that the impact of delusions, for example, may be limited to a discrete area of mental functioning. Although this belief awaits definitive empirical verification, it indicates the possible utility of a test of rationality directed to the specific decision at hand, rather than to the individual's general functioning.

Frequently, however, there is difficulty in drawing the required causal links between the presence of even clear-cut delusional phenomena and the subject's specific decision. It has been suggested that one means of so doing may be to demonstrate that in the absence of the subject's delusions, the decision would have been made differently. But that may be to place greater emphasis on the outcome of the decision than on the process by which it was derived, the latter comprising the core of the rationality standard. In addition, except in rare cases, such proof would be extremely difficult. More practical would be a test in which the presence of any of the signs or symptoms noted above in the subject's chain of reasoning about participation in research would raise a serious but rebuttable doubt as to the subject's rational manipulation of the relevant information.

D - Appreciation of the Nature of the Situation (See Table IV)

The strictest standard for competency requires, once understanding has been attained, that the rational manipulation of information take place in the context of the subject's appreciation of the nature of his situation. Appreciation is distinct from factual understanding in that it requires the subject to consider the relevance to his immediate situation of those facts he has previously understood in the abstract. It differs from the rational manipulation of information by requiring that the subject take certain crucial data into consideration, rather than merely asking him to manipulate rationally whatever information is already at hand. This has been phrased in a variety of ways, asking that the subject: "appreciate the consequences of giving or withholding consent," (28) have "a sense of who he is and why he is agreeing," (21) recognize, "in a mature fashion, the implications of alternative courses of action and appreciate both cognitively and affectively the nature of the thing to be decided," (29) or "appreciate what is relevant to forming a judgment of the issue in question - i.e., . . . consider relevant evidence." (10)

"Appreciation" has been widely discussed in relation to the somewhat analogous issue of criminal responsibility. According to the formulation of the Model Penal Code of the American Law Institue, the lack of "substantial capacity . . . to appreciate the wrongfulness of his conduct" is one situation in which a defendant will be held to be non-culpable. (30) Appreciation, in this sense, is taken to be an affective, as well as a cognitive, recognition of the nature of the situation. (31) This precludes finding culpable an individual who knows in the abstract that to murder is wrong, but who believes that divine writ has relieved him of the need to adhere to that rule. In the research setting, using this standard, an individual who understood the nature of the proposed procedures and could rationally evaluate their risks and benefits, but who believed that he was being asked to participate in an exclusively therapeutic, rather than an experimental, process would be found to be lacking in capacity to consent.

Suggestions as to the components of the situation whose existence ought to be appreciated by the subject include: that the subject has a problem or psychiatric condition appropriate for study, (17) that the proposed procedures are intended to achieve research ends and not only (if at all) therapeutic ends (32), that there may be both treatment and research staff members involved in his care and that their roles may differ, (17) that the treatment that is offered may have been selected on a randomized basis, (33,34) that both he and his caretakers may be blind to the nature of the treatment, and that he may receive placebos. An additional proposal is that the subject have an "awareness of how others view the decision, the general social attitude toward the choices and an understanding of his reason for deviating from that attitude" if he chooses to do so. (20)

The extent of the lack of appreciation of some of these elements has been demonstrated in studies that revealed: that without a clear-cut explanation most subjects were not able to infer that research was going on (35); that a majority of parents of pediatric research patients did not recognize the research nature of the hospitalization (32); that only medically trained subjects were able to appreciate fully the risks in a drug study despite extensive explanation (35); that even when patients were told that they were being given a placebo, they still ascribed therapeutic powers to it (37); and specifically with regard to psychiatric patients, that patient-subjects have difficulty in distinguishing beneficial from non-beneficial aspects of research (38); that 68% of schizophrenic patients failed to cite their illness as the reason for treatment (39); and that only 46% of a sample of newly admitted voluntary psychiatric patients could clearly acknowledge the presence of psychiatric problems. (40)

Relevant psychiatric aspects - The major psychopathologic mechanism that can impair appreciation (given the ability to rationally manipulate information) is denial (25), sometimes termed lack of insight. Denial can affect the subject's appreciation of the fact and severity of the illness or condition, (41) the fact that research and not merely treatment is being proposed, the possibility of improvement with and without the research procedures, and the scientific methodology of the study (e.g., placebo, double blind, randomization). Other factors that may influence appreciation include the capacity for abstract, as opposed to concete, reasoning (affected by intelligence, level of education and "maturity" (19), as well as psychosis and organic brain damage); and psychotic-level distortion, nihilism, and hopelessness-helplessness. The law, in some non-pathological circumstances, has traditionally included a variant of the "appreciation standard" for determining competency. Thus adolescents, who can both understand and rationally manipulate information, are nevertheless enjoined from making unaided treatment or research decisions, presumably on the basis of lacking the maturity required for genuine appreciation.

Testing for competency - A subject's ability to appreciate, in general, can be estimated by the usual techniques of judging insight and determining the presence of psychotic-level defenses. Specifically with regard to the research setting, the subject's appreciation can be tested by examining his grasp of the factors discussed above. Whether the extent of the subject's appreciation needs to coincide precisely with the investigator's is a controversial topic. Some commentators have suggested that, in a therapeutic setting, the patient need only "understand the nature of the mental condition which the psychiatrist believes him to have," without necessarily agreeing with that judgment. (15,42) Such a standard, however, more closely resembles a factual understanding test than a genuine test of appreciation. Although some people may be uncomfortable with such a criterion, of necessity the subject's views (e.g., on the presence or absence of illness or the results of accepting or refusing participation) must ultimately be measured by their correspondence with the consensus of knowledgeable (usually professional) opinion on those issues.

Choosing the Standard

Despite wide variation in the wording of many attempts to define the standards for competency, they appear, as shown above, to be classifiable into four general categories. Rather than deriving a single standard for competency from this discussion of the relevant mental functions and the psychopathologic states that may impair them, one is left with a range of testable functions that, depending on where the line is drawn, can yield multiple standards for competency of varying stringency. Further, it is clear from this approach that any of the four resulting standards, or some combina- of them, are "legitimate" as long as they can be justified from some reasonable policy perspective.

Although the place at which one chooses to draw the line ought to be determined by the policy-oriented goals that one is seeking to attain, difficulties arise when more than one policy goal is sought, when the desired goals are incompatible, or when no consensus can be attained on the desired goals. The ultimate standard for competency is thus almost certain to be a compromise that seeks to maximize the desirable effects of applying a given standard while minimizing the undesirable ones. This process becomes clearer when consideration is given to the possible goals that one might attain by varying the standard by which a subject is considered competent. Such goals inevitably include a mixture of concerns relating to the societal values that we wish to implement and to the preferences we wish to confer in these values. The values at stake in the choice of a standard for competency to consent to research inevitably include a mixture of symbolic and instrumental concerns.

Autonomy - Also referred to as self-determination, the principle of encouraging autonomy for the subject has been considered one of the central goals underlying the entire doctrine of informed consent. (24,43,44) By requiring comprehensive disclosure of information to the experimental subject, informed consent is said to return to him maximal power to decide what should or should not be done with his body. Insofar as many writers see the power to make one's own decisions as the essential attribute of autonomous functioning, they argue for a minimal standard for competency or for abolishing the requirement for competency altogether. (18,45) A standard that requires no more than "evidencing a choice" would maximize autonomy thus conceived.

Rational decision-making - The promotion of rational decision-making is seen as a good in itself by several authors, (43,44) even those who at the same time view maximizing subject's autonomy as a primary goal of informed consent. Rationality in decision-making would seem to require a very high standard for competency, at least "rational manipulation of information," and probably "appreciation of the nature of the situation," since the rationality of the outcome when such appreciation is lacking may well be in doubt.

Beneficence - Somewhat out of fashion these days as a goal of policy-making, and usually omitted from discussions of the objectives of informed consent, beneficence represents the ethical imperatives both to protect others from harm and to do good whenever possible. (24) So construed, beneficence favors a stringent standard for competency, at least "rational manipulation of information" and probably "appreciation of the nature of the situation," in order to achieve three ends: (a) honoring autonomous decisions only when the subject's capacity to behave autonomously is clearly present; (b) protecting those who, lacking competency, would consent to research that involved risk to them, and (c) assuring that incompetent subjects who refuse participation that might be highly advantageous to them are nonetheless permitted (some would say compelled) to benefit by participating in the research project.

Although this is the way in which the topic is usually discussed, it is of interest that the entire doctrine of informed consent can be seen in terms of beneficence, rather than as a requirement only designed to promote autonomy: to the extent that the requirement for informed consent limits the freedom of the individual to consent to research under conditions that may be acceptable to him, but not (because risk is involved) to society as a whole, it limits an individual's exercise of autonomy for the sake of his protection.

Respect for persons - This term tends to be used in a variety of ways, but has been defined as "using a person as an end and not a means" (46), as "protecting the patient's status as a human being" (44) and as not taking advantage of the subject. (Shah S, personal communication). The goal of avoiding fraud and duress would also seem to belong here. (44) As an ethical objective, respect for persons carries within it the tension between allowing as much autonomy as the individual can reasonably manage and providing protection to those with diminished autonomy. It therefore encourages a compromise between the goals of autonomy and beneficence and may point towards an intermediate standard such as "factual understanding" or "rational manipulation of information."

Justice - Highlighted by the Belmont Report as a primary ethical consideration in undertaking research, (24) justice in this sense is usually conceived of as distributive justice: assuring that the burdens of participating in research do not fall inequitably on certain groups. This goal can be accomplished by raising the level for competency required from those groups one wishes to protect. In effect, this is what the *Kaimowitz* court attempted to do, by raising the level of competency required from a prisoner to the point at which no prisoner could meet it. The court manipulated the level of competency required to enforce its conviction that the participation of prisoners in psychosurgical procedures under any circumstances was undesirable.

On the other hand, there has been some attention given to the distribution of the benefits of participation in research, such as enhanced self-esteem, and consequent objections to being treated differently have been raised on behalf of some groups. It has been argued, for example, that creating special regulations governing research with the elderly would contribute to an unfair characterization of older people as generally senile and in need of special protections; (47) heightened restrictions on the use of certain classes of subjects, such as the mentally ill, are also felt to deprive those most in need of advances in research of the possibility of progress. (48)

Insofar as undesirable effects are likely to accrue disproportionately to vulnerable groups only to the extent that their ultimate choices about participation in research differ from those of the population at large, the argument may also be made that one must examine the nature of the decisions of presumptively incompetent subjects as a group before one can legitimately require that they receive special protection. One study has shown that the distribution of decisions about participation in hypothetical research projects was the same in a group of medical patients as in a group of psychiatric patients. (49) Assuming this finding can be validated, it may well bring into question the usefulness of excluding subjects on the basis of incompetency in protecting autonomy, assuring beneficence and respect for persons, and achieving justice for the mentally ill.

Encouragement of research - Certainly some researchers feel strongly that the requirement for informed consent can serve to deter the pursuit of important areas of knowledge. (50) It seems apparent that varying the level of competency required from subjects can affect their absolute availability, the ease with which they can be recruited, and the expense that their recruitment entails. As self-evident as that proposition appears, it is unclear, pending empirical investigation, in which direction the standard of competency should be moved to encourage research. A low standard of competency is advocated both by researchers, who believe that most subjects given a choice will consent to their procedures, and by lawyers, who are more interested in autonomy than in research and believe that most subjects will refuse. A favored solution of many researchers is to abolish the requirement for competency to give informed consent altogether, replacing it instead with a rigorous, objective examination of the risks and benefits entailed by the project. Once some outside, knowledgeable committee has concluded that the benefits of the study outweigh the risks, it is advocated that subjects be permitted to consent regardless of their level of competency. (51)

It may furthermore be that decisions made about research participation, even if uninformed, or pressured, or made by people of dubious competence, may not differ from the decisions that all of us make in everyday life, such as when buying a used car or choosing a brand of shampoo. If it is desirable to treat research no differently from those other situations (this may relate to the desire to encourage research or to some sense of fairness), then the level for competency should be set at the same presumably low level that obtains generally. While experimental data would be required to ascertain what that level is in a variety of settings, the increasing technical complexity of our society makes it likely that many decisions in everyday life are made without appreciation of their consequences, without the ability to manipulate in a rational manner the information that is provided, and probably without full knowledge of the relevant details. Such an argument would militate towards a low standard of competency for consent to research (although it does not affect the desirability of providing information to the subjects), perhaps merely "evidencing a choice."

Subject satisfaction - If, in the same sense that we wish to maximize autonomy, we are also concerned with the level of satisfaction that subjects display concerning their participation or failure to participate in research, an attempt might be made to vary the level of competency required to take that into account. Those who are excluded by too high a standard (or included by means of a proxy consent rather than their own choice) and those who were included by too low a standard and later feel trapped by the decision that they were permitted to make might both desire the level at which the line is drawn to be adjusted accordingly. Only empirical data on the numbers of subjects who fall into each group will allow this end to be accomplished.

Test Administration - A prime consideration in many judicial formulations of standards and procedures, the ease of administration may also be an important factor in selecting a standard for subjects' competency. Ease of administration refers not only to the time and effort required to perform the assessment, but also to its reliability, that is, its reproducibility and the possibilities for manipulation and corruption. Along these lines, some authors have objected to standards for competency carried out at any level higher than "factual understanding" because of the inherent difficulties in determining the rationality of thought processes and the subject's appreciation of the nature of his situation. (23) Following a similar line of reasoning, objections have been raised to the use of any standard higher than "evidencing a choice." (18) Nonetheless, the data needed for the selection of an appropriate standard by means of the reliability criterion do not yet exist; they await empirical testing of a variety of definitions of competency in a controlled setting.

The choice of a standard may also be affected by the sensitivity and specificity of the procedures that must be used to establish whether the requirements of a particular standard have been met. A highly sensitive test yields a low number of false negatives; a highly specific test yields few false positive findings. (52) Depending on one's tolerance for incompetent subjects to be included in research or for competent ones to be excluded (which may relate to how highly valued are the factors of autonomy, beneficence, and encouragement of research), one might want to choose a standard which when linked to the procedures used to test for competency, exhibited one or another of these characteristics. Such a characterization of any of the standards or the procedures used to test for them, however, also awaits experimental definition.

Temporal Considerations

Rather than setting a unitary level of competency for all subjects at the time of their entry into a research project, one might assume that they will become more understanding, better able to manipulate the information, and more appreciative of the nature of the situation as they go along. Reflecting this expected change, one might require a relatively low standard for competency at the time of entry into the project (for example, the "ability to understand") but also require reconsent as the project proceeds, with a higher standard utilized at that time. This approach, which emphasizes "experiential," as much as informed, consent represents a means of reconciling autonomy, beneficence, and encouragement of research.

Conclusion

It is apparent that before the appropriate standard for competency to participate in research can be selected intelligently, a good deal of additional empirical data, as well as further clarification of the requisite moral imperatives, is required. At this point in time, it is difficult to say with assurance that we know where to draw the line in order to insure the attainment of any of the policy goals outlined above. What is needed is empirical testing of the reliability and validity of the various ways of characterizing competency, a characterization of the general population and of discrete populations of particular concern according to these standards, and a comparison of the decisions made by those who meet or fail to meet a particular standard. Only then will we be able to protect the variety of interests involved in human experimentation in a meaningful way.

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Table I

Evidencing a Choice	
Communicates decision about participation	
a. manifests consent	(18)
b. expresses positive interest in taking part	(17)
c. cooperates appropriately in early procedures involved in study	(17)
d. gives responses (any-none) to pertinent questions	(18)

Relevant Psychiatric Aspects

- Mutism
  - a. catatonic stupor
  - b. severe depression
- Catatonic excitement
- Mania
- Profound psychotic thought disorder (e.g., word salad)
- Marked ambivalence
  - a. schizophrenia
  - b. severe obsessive states

TABLE II

Factual Understanding (Encompassing ability to understand and/or actual understanding)		Relevant Psychiatric Aspects	
Has cognitive capacity to consider the relevant issues		Intelligence a. IQ	(24)
Understands the nature of the procedure, its risks, and other relevant information	(8)	(1) mental retardation (2) some organic states	
Understands the nature and likelihood of success of the proposed treatment and ... its risks and side effects	(15)	b. adaptive capacity to tasks of everyday life (1) chronic psychiatric illness	
Knows the available options, their advantages and disadvantages	(19)	(2) effects of institutionalization	
Knows that he has a choice to make	(20)	Language Skills	(24)
Knows who he is, where he is, what he is reading, and what he is doing in signing the form	(21)	Attention a. acute psychotic episodes Orientation	(25) (17)
Knows the consequences of participation or non-participation	(22)	a. acute psychotic episodes Recall and recent memory	 (25,17)
Knows up to fourteen separate items which must be considered, e.g., availability of compensation for injuries	(13)	a. acute psychotic episodes b. chronic schizophrenia All above factors impaired by a. long-standing brain damage	 (26)
		b. acute toxic states	

Table III

Rational Manipulation of Information	
How information is used in decisionmaking process	
a. good judgment	(25)
b. is rational	(24)
insane delusions absent	(7)
c. tests reality	(25)
d. has decisionmaking capacity	

Relevant Psychiatric Aspects		
Delusions	(28,15)	
Hallucinations		
Loosening of associations or other severe thought disorder		
Extreme phobia or panic	(20)	
Anxiety	(25)	
Euphoria	(20)	
Depression	(20)	
Anger		
Agitation		
Obsessive preoccupation		
Excessive dependency	(20,25)	)
Passivity	(25)	)Volun-
Unwarranted trust	(25)	)tariness?

112

113

Table IV

Appreciation of the Nature of the Situation

Appreciates the nature of the situation (affectively as well as cognitively)
Appreciates the consequences of giving or withholding consent (28)
Senses who he is and why he is agreeing (21)
Recognizes "in a mature fashion," the implications of alternative causes of action and appreciates both cognitively and affectively the nature of the thing to be decided (29)
Appreciates what is relevant to forming a judgment of the issue in question - i.e., . . . considers relevant evidence (10)
For all of the above, "appreciates"
  a. that he has a problem or psychiatric condition appropriate for study (17)
  b. that the proposed procedures are intended to achieve research ends and not only (if at all) therapeutic ends (32)
  c. that there may be both treatment and research staff members involved in his care and that their roles may differ (17)
  d. that the treatment that is offered may have been selected on a randomized basis (33,34)
  e. that both he and his caretakers may be blind to the nature of the treatment
  f. that he may receive placebos

) as relevant for a given research project

Has awareness of how others view the decision (20)

Relevant Psychiatric Aspects

Denial (lack of insight) about: (25)
  a. fact and severity of illness or condition (41)
  b. fact that research and not merely treatment is being proposed
  c. the possibility of improvement with and without research procedures
  d. the scientific methodology of the study (e.g., placebo, double blind, randomization)
Capacity for abstract thinking, affected by
  a. IQ
  b. education
  c. psychosis
  d. organic brain damage
  e. experience (e.g., age, "maturity") (19)
Psychotic level
  a. distortion
  b. projection
  c. nihilism
  d. hopelessness-helplessness

Informed Consent and Competence:
A Review of Empirical Research

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Over the past twenty years, interest in informed consent in medical treatment and research has burgeoned. Evidence of this growing concern is the large number of published articles on consent in this twenty year span. Woodward (1979) reports that the number of articles about human experimentation and informed consent increased six-fold in the period following 1960 as contrasted with the twenty year period prior to 1960. This growth can be attributed to two related causes, the first of which is a heightened "consumerism" on the part of patients. Previous abuses have been documented as the reason for this movement (Stuart, 1978). Federal regulations were enacted to provide some measure of protection to research participants (Federal Register, 1974) and the informed consent doctrine became more incorporated into elements of medical practice (Deveaugh-Geiss, 1979; Morris et al., 1977; Silberstein, 1974). The second cause of this increased interest in issues surrounding human experimentation is the appearance of "informed consent" or lack of it as an issue in lawsuits against medical practitioners (Meisel, 1977).

In reviewing the published articles on the consent process, the majority of them have been opinion or position papers (Burra et al., 1980; Culver, 1980; Loftus and Fries, 1979; Vaccarino, 1978). They serve to clarify the issues (Gray, 1978) involved in obtaining consent and aid in the development of a uniform doctrine. The opinions expressed in these articles run the gamut from the view that informed consent is the "absolute right" of a patient and is in no way detrimental to the goals of research (McLean, 1980; Park et al., 1967) to the opinion that informing the patient serves only to terrify him and cause undue anxiety, destroy the nature of the doctor-patient relationship, and may severely impede the progress of research (Coleman, 1974; Park et al., 1966). Further, opinion also suggests on the one hand that truly informed consent is a myth (Leeb et al., 1976) a fiction or illusion (Goin et al., 1976; Hirsch, 1977; Laforet, 1976). While on the other hand, it is believed that a "reasonable" consent can be obtained (Alfidi, 1971).

This diversity of opinion is also expressed with respect to obtaining consent from patients whose competence is suspect as in the case of severely disturbed psychiatric patients. Some view the presence of mental illness as limiting the possibility of obtaining informed consent (Pryce, 1978). Others believe consent can be meaningfully obtained from many of these patients.

While opinion plays an important role of identifying and clarifying the issues, it is rather surprising that many opinion papers which address ability to give consent, do so without an empirical base for their positions. The questions surrounding informed consent are sorely in need of solid empirical investigation (Stanley and Stanley, 1981) and some research efforts have recently been made in this direction. It is this empirical work which serves as the basis for this review.

This paper will highlight the major empirical findings on informed consent. Instead of detailing precise results from each empirical study, it will focus on unanswered questions which emanate from the empirical work conducted to date.

The research on consent falls into four major areas: 1. disclosure and comprehension of consent information, 2. patient subjective reactions to consent information, 3. methods of decision-making in the consent process, and 4. competence of the patient or research participant to give consent. This last topic, competence, could be subsumed under research on comprehension but for purposes of this review, those studies which address populations of questionable competence will be reviewed separately. Further, those studies which investigate consent-to-standard treatment will be reviewed along with those which examine consent to research. The results of these studies can be applied to consent to research as well as to patients whose competence is suspect.

Comprehension and Disclosure

The first group of empirical data to be reviewed are those studies which investigate comprehension of consent information by patients. The largest body of empirical research on the consent process fall into this category. Medical patients are the most frequently investigated. More than twenty studies have assessed understanding of consent information by patients (e.g. Bergler et al., 1980; Cassileth et al., 1980; Hassar and Weintraub, 1976; Kennedy and Lillehaugen, 1979; Marini et al., 1976;

Penman et al., 1980; Robinson and Merav, 1976; Schultz et al., 1975; Singer, 1978). The prototype of these studies is as follows. Patients are given a consent form for either a research protocol or standard treatment, the form is usually read to them by a physician or investigator. Patients are then asked questions regarding their knowledge of the consent information. The point in time that they are asked these questions varies from immediately afterward to several months later. In the latter case, the study becomes one of testing recall instead of comprehension.

While it is difficult to make comparisons across studies as a result of different methodologies, it is generally concluded that comprehension of consent information, irrespective of assessment time, is poor. Overall comprehension ranges from approximately 35% to 80% of the total information conveyed. Patients tend to be best informed about their diagnosis and the proposed treatment (for example, the name of the drug they were to take) and least knowledgeable about alternate treatments available and risks including side effects of drugs and possible complications of surgical procedures. In addition, some studies of research patients demonstrate that many were not aware or did not acknowledge that they were, in fact, participating in a research study (McCullum and Schwartz, 1969; Park et al., 1966).

While results of these studies are, at first glance, discouraging about the prospects of obtaining consent, most of the studies have limitations which make it difficult to consider them conclusive (Meisel and Roth, 1980). First, in several studies we do not know exactly what information was conveyed to the patients (Cassileth et al., 1980; Goin et al., 1976; Priluck et al., 1979). Further, some studies gave patients the consent form to read and then tested knowledge of this form. We do not know if, in fact, all patients read the form (Olin and Olin, 1975). In this same vein, the amount of instruction given to patients varied from study to study. In some, instruction was minimal with no particular effort made to convey the consent information (Benson et al., 1977). In other studies, investigators went through a good deal of instruction with patients (Faden and Beauchamp, 1980). Across studies, in general, greater instruction appears to be associated with greater understanding. This conclusion must be tentative, however, since most studies investigate only one level of instruction (i.e. consent form, videotape aids, etc.) and differences among sample characteristics and medical procedures for which consent was to be obtained vary greatly (Arluke, 1980; Muss et al., 1979; Stuart, 1978).

Another factor which makes it difficult to draw generalizable conclusions is that in many of the studies we do not know the level of complexity of the language of the consent form that was related in the consent session. Grundner (1980) and Morrow (1980) suggest that most consent forms are written in highly technical language. This may account for some of the poor comprehension attained in the empirical studies. However, this is a speculation since most studies do not report the readability of their consent material. Epstein and Lasagna (1969) conducted one of the only studies which systematically varied complexity of consent material. They presented three different consent forms of varying length to normal volunteers. They found that comprehension was inversely related to the length of the consent form. Therefore, greater comprehension may be achieved by increasing instruction and decreasing the complexity of material. A simple technique such as giving the patient a consent form to take home with him prior to signing it increases knowledge (Morrow et al., 1978). Also suggested are two-part or three-part consent forms, objective tests, videotape aids (Barbour and Blumenkrantz, 1978; Grabowski and Mintz, 1979; Schwartz, 1978; Silberstein, 1974; Stuart, 1978, Williams et al., 1977). Other studies have investigated the modality of disclosure -- i.e. how the information is conveyed to the patient -- to determine if comprehension systematically varies according to type of presentation -- written information, videotape, discussion groups (Faden, 1977; Faden and Beauchamp, 1980). These initial studies show that modality does not seem to make a difference in level of comprehension. However, comparing innovative modalities of disclosure with the traditional one-to-one doctor-patient model is, as yet, untested. There is some suggestion (Muss et al., 1979) that instruction given by health professionals in addition to that given by the physician improves comprehension of consent information. But it is unclear whether this improvement is simply due to repeated exposure to the consent material or as a result of a qualitative difference in explanations given by doctors and other health professionals.

Comparing studies of comprehension of consent information is further complicated when the methods for assessing comprehension are examined. Some investigators use multiple choice or true-false tests as a means of assessment while others utilize open-ended questions with coded responses. Relevant literature on learning and psychological testing has shown that tests of recognition, e.g. multiple choice tests, are easier than tests of recall, i.e. open-ended questions. Therefore, comparing results of studies which use open-ended questions with objective questions is problematic.

A further difficulty in comparing these studies lies in the fact that immediate understanding and recall at some later point in time are often treated interchangeably. However, results show, not surprisingly, that retention of information declines over time. The utility of assessing retention of all consent information must be questioned. Certainly it is important that a research subject remember that he has the freedom to withdraw from an experiment but it may not be necessary that he keep all the consent information in mind several weeks or months after the initial decision. Further, the fact that an individual forgets information does not mean that it wasn't used at the time of the decision and then forgotten as part of the normal forgetting process.

It must be noted that in the studies reviewed here, there has been an assumption made by most of the investigators that knowledge of the consent information as measured by some form of objective test is equated with comprehension of that information. This is a questionable assumption. If an individual is able to repeat what he has been told, it does not necessarily mean he understands that information. In other words, knowledge is a necessary but not sufficient condition for understanding. A novel approach such as that taken by Mellinger et al. (1980) seems to be called for. They developed a three-part assessment of comprehension which includes an objective test which requires subjects to make judgments about a series of statements. Illogical judgments indicate a lack of comprehension.

Lastly, the sample characteristics of the patients must be taken into account when we examine comprehension. Many of the studies have examined understanding of consent information by medical patients who have serious illnesses. Others have looked at the less seriously ill and some have researched the "normal" volunteer (i.e., those without medical illness). Hospitalized and non hospitalized patients have been studied. Comparability of these subject groups cannot be assumed. The ill patient is under more emotional stress than the healthy volunteer. This stress may interfere with comprehension of consent information. Further, differences may be found between the hospitalized and non-hospitalized patient. There is some research which suggests that hospitalization itself makes an individual feel more vulnerable and this in turn may influence comprehension of consent information. Cassileth et al., (1980) found that ambulatory patients demonstrated greater comprehension of consent information for cancer treatment than those who were bedridden. Perhaps bedridden patients were preoccupied with more serious illness. Further, educational level and intelligence have shown some relationship with comprehension of consent information (Cassileth et al., 1980) although this is not a consistent finding.

Overall, the comprehension level of consent information is not very high. However, instructional aids seem to increase comprehension. In general, conclusions from these studies of comprehension must be drawn with caution because of their limitations.

Patient Reactions

In addition to studying the amount of consent information that patients understand, some investigators have conducted studies on how patients feel about being informed (Alfidi, 1971; Denney et al., 1975; Golden and Johnston, 1976; Lankton et al., 1977). This area of investigation was popular a few years ago when the merits of informed consent were being hotly debated. This research typically was designed to assess whether informing the patient was harmful. To a large degree, this point is moot since consent is now required for most research projects and not informing the subject is no longer a possibility. Initial efforts are being made to redirect this research toward determining the least anxiety-producing manner for informing the patient (Faden, 1977; Faden and Beauchamp, 1980).

Patient reaction to consent information is typically assessed by asking patients whether the information disclosed in the consent session made them upset or anxious. While there are anecdotal reports that the disclosure made patients anxious or fearful, statistical studies find no differences in anxiety levels, either self-reported or by physician observers, between informed and uninformed patients (Denney et al., 1975; Lankton et al., 1977; Houts and Leaman, 1980). While two studies without uninformed controls (Alfidi, 1971; Houts and Leaman, 1980) found that consent information disturbed about 40% of the patients, only 1% decided not to go ahead with the recommended procedure and 97% of the people regarded the information as useful. It is interesting to note that one study (Denney et al., 1975) found that anxiety levels post-operatively were lower in informed rather than uninformed patients. This finding suggests that knowledge of expected results make the actual results more emotionally tolerable and less frightening. In fact, this notion serves as the basis for pre-surgical counseling which prepares patients through support and information.

In a study of family planning clinic patients, different methods of disclosing information to the patients did not have an impact of patients' level of anxiety (Faden, 1977). About twenty-five percent of the patients reported feeling more anxious than usual following the disclosure of information. However, the same percentage of patients who were faced with making the decision about contraception also reported more anxiety than usual despite the fact that they had not received the detailed information.

Thus, when conducting studies in this area it is important to attempt to separate out normal anxiety induced by making a decision about a medical problem from anxiety induced by detailed information about the procedure. Further, it would be useful to conduct similar studies with medically ill patients to determine whether they respond differently than patients who are healthy (Golden and Johnston, 1970). A study which did examine chronically ill patients found that physicians who sounded angry and anxious but whose speech content was sympathetic had patients who were more content. This suggests that a very complicated set of factors are involved in patients' reactions in a medical setting (Hall et al., 1980).

Overall, this area of investigation would seem to be most fruitful if efforts were placed, not in looking at whether consent information makes people upset or anxious, but instead toward finding the least anxiety-provoking manner in which to disclose information.

Decision-making

A small number of studies have investigated factors which influence patient decision-making in the consent process. Some studies have shown that people feel that they have no choice and must participate (McCullum and Schwartz, 1969). Other studies do not find this and the primary focus of them has been to determine whether disclosure of risks discourage patients or research subjects from giving consent (Alfidi, 1971; Lankton et al., 1977). In a study of risk disclosure for anesthesia, patients did not refuse the procedure following detailed information about the risks (Lankton et al., 1977). Similarly, in two studies only a few patients refused angiography following a detailed risk disclosure (Alfidi, 1971). Perhaps the best known study in this area was conducted on kidney donors (Fellner and Marshall, 1970). This study was designed to determine whether kidney donors utilized risk information in their decision to donate a kidney. It was found that decisions were made long before any detailed risk disclosure was made and further that disclosure had little impact on the donors. However, more recent research (Stanley et al., 1980, Stanley et al., 1981) has shown that participation in hypothetical research projects varies according to the risk of the project.

A few studies have attempted to relate comprehension of consent information to decision-making (Epstein and Lasagna, 1969; Stuart, 1978). Tentatively, findings seem to indicate that higher levels of comprehension are associated with higher rate of agreement. However, interpretation of these findings are problematic because the risk-benefit ratios of the procedures must be known in order to determine whether the patients' affirmative decisions were sensible.

As an outgrowth of the studies which showed that risk disclosure does not seem to influence decision-making with regard to medical procedures, some investigators have begun to identify factors which do influence decisions. In a study of participation in psychology experiments (Geller and Faden, 1979), the relative influence of standard consent information and personal testimony of one individual was examined. While recall of consent information was affected by testimony which contradicted it, the decision to participate was not affected. In another study, subjects reported that disclosed information was not the primary determinant in decisions regarding contraception. Instead, personal feelings were reported to have a greater influence on the decision (Faden and Beauchamp, 1980). As an extension of this work, it seems worthwhile to utilize and adapt some of the techniques developed by investigators who research decision-making and information processing (Janis and Mann, 1977; Jungerman, 1980). For example, it seems worthwhile to try to adapt the technique of "policy capturing" to research on informed consent. In addition to asking subjects what influenced them, they could be placed in a variety of hypothetical situations and asked to make a decison about participation. In this way, the patient's ability to report influences, an ability which is not completely reliable, would not be so heavily depended upon. This hypothetical approach with its pitfalls can be balanced with the patient self-reports for a fuller picture of the decision-making process.

Competency

Competency to engage in the consent process has been the least researched area in the informed consent literature. A major difficulty with conducting research on competency lies in the fact that there is no standard definition of competence, (Meisel et al., 1977; Roth et al., 1977), no accepted test of competency (Appelbaum et al., 1981a; Appelbaum et al., 1981b; Dabrowski et al., 1978) and no clear agreement on the appropriate dividing line between competence and incompetence. In studies of comprehension, what one investigator believes as signifying competence (Woodward, 1979) another believes indicates incompetence (Bergler et al., 1980). Further, agreement is lacking on which groups of patients should be suspect as having "uncertain competence." Mentally ill patients have been identified as one such group and the few empirical studies on competency have focused on the mentally ill. However, other populations may also fall into this category of "questionable competence." These groups are the elderly, children, the mentally retarded and those patients suffering from organic brain syndrome. Empirical investigation of these individuals is lacking.

The empirical evidence that is available with respect to the mentally ill presents a somewhat mixed picture. Under the rubric of "mentally ill," are primarily schizophrenic and psychotically depressed patients. One conclusion which can be safely drawn with respect to the mentally ill is that they certainly do no better than medical patients in the consent process.

The evidence that they are less able to give consent is somewhat equivocal and to a certain extent depends upon the definition of competency which is utilized. With respect to comprehension of consent information, a few studies have assessed psychiatric patients' ability to understand consent information (Appelbaum et al.,1981a; Grossman and Summers, 1980; Soskis and Jaffe, 1979; Roth et al., 1980). In general, patients do not have a very high level of understanding of consent information. However, when comparing studies of medical patients' comprehension with studies of psychiatric patients, understanding in both groups seem to be fairly equal (Grossman and Summers, 1980; Soskis and Jaffe, 1979). An example of this is seen in one study which found that schizophrenic patients understood about 50% of the material on a consent form which was read to them (Grossman and Summers, 1980). In a direct comparison of psychiatric and medical patients, it was found that schizophrenic patients were more aware of the risks and side effects of their medication than were medical patients (Soskis, 1978). On the other hand medical patients were better informed about the name and dose of their medication as well as their diagnosis. The poor knowledge of diagnosis by psychiatric patients may be partly a result of a general reluctance by hospital staff to tell patients that they have schizophrenia. Related to the comprehension level of psychiatric patients are studies which have examined the literacy skills of these patients. Despite the fact that psychiatric patients' comprehension of consent information seems to be equal to medical patients, research indicates that their reading comprehension scores were only at the fifth grade level (Berg and Hammitt, 1980; Coles et al., 1978). As a result, a suggestion is made that hospital documents be simplified for psychiatric patients (Berg and Hammitt, 1978) as some have suggested for medical patients.

In studies of psychiatric patient's ability to consent to hospitalizaiton, the results indicate that level of knowledge of patient rights is relatively poor (Appelbaum et al., 1981a; Palmer and Wohl, 1972). However, as the authors mention it is important to know whether medical patients would score higher than psychiatric patients and also it is important to separate out what was the result of patients' inabilities and deficient information-giving on the part of the hospital admissions service. In contrast to the studies which conclude that psychiatric patients may not be competent to give consent, one study concludes that 93% of the patients give a valid consent (Dabrowski et al., 1978). However, the standard for competency was set much lower than the other studies described here.

In a study of consent to ECT (Roth et al., 1980) it was found that about 25% of the patients were found to be incompetent based on their understanding of consent information and independent judges' opinions about their comprehension. This study is the first which has taken a comprehensive approach by coordinating objective information (i.e., patient comprehension) with legal judgments and psychiatric opinions and seems to be a fruitful direction for further research.

A few studies of psychiatric patients have examined the relationship between understanding and the decision to consent or refuse the proposed procedure (Grossman and Summers, 1980; Roth et al., 1980). They found that, like medical patients, psychiatric patients who understood more of the consent information tended to agree to the procedure more often.

With respect to patients' rationale for deciding to agree to a treatment or research protocol, results are not clear-cut. One study found that the risks of psychotropic medication did not play a role in patients' decisions to refuse medication (Applebaum and Gutheil, 1980). Psychological factors were cited as primary reasons. It is difficult to compare these results with those from medical patients because no medical study to date has attempted to delineate the psychological factors examined in the psychiatric study. In a study (Stanley et al., 1980; Stanley et al., 1981) which examined psychiatric and medical patients' willingness to participate in a series of hypothetical studies, no differences were found between the two patient groups. Both psychiatric and medical patients agreed to participate in the studies in a manner which was consistent with the level of risk attendant to the study protocol. It is important to conduct a parallel study which investigates participation rate in actual projects.

Overall, the empirical research on competency shows that psychiatric patients do have some impairment in their abilities.

However, some of the research also shows that in some respects they do not differ from medical patients. As a result, further studies which utilize comparison groups, particularly medical patients, are vital if conclusions are to be drawn about any one group of patients. In addition, it is also important to state precisely the standards used for determining competency so that comparisons can be more readily made from study to study. Conclusions, such as only a "quarter of the patients could give true consent" (Pryce, 1978), are helpful only if the criteria for true consent are disclosed.

Conclusions

This review has attempted to highlight major findings on informed consent in four areas: 1. disclosure and comprehension; 2. patient reactions to the consent process, 3. the decision-making process and 4. competency to give consent.

Areas for further investigation were particularly emphasized and can be summarized as follows:

1. Further study of comprehension of consent information should include careful documentation of what was disclosed to the patient in order to make assessment of comprehension meaningful. Also, a more creative approach than straightforward knowledge tests, to the assessment of comprehension is called for.

2. Comparison groups are of utmost importance if our findings are to be interpreted meaningfully. It is not possible to conclude that one group of patients is not competent if we

do not have a standard of comparison.

3. In this regard, clearer criteria for competency to consent to research should be developed. Those criteria should be explicitly stated in each study so that comparisons can be more readily made. The dividing line between competency and incompetency should be systematically formulated.

4. Multivariate studies which examine the interrelationships among relevant variables should be undertaken. For example, the relationships among methods of disclosure, rationality of decision-making, comprehension of consent information, and final consent decision has been investigated only to a limited extent. The multivariate approach offers the advantage of comparing different means of assessment and methods on the same population. As a result, findings can be stated more conclusively.

5. In the same vein, comparisons of patient characteristics across patients groups seems to be important. Factors, such as the effects of hospitalization on the ability to give consent, have not been investigated. Relevant research is of practical value with respect to timing of consent. Other factors which may influence consent such as whether or not the patient is medicated, educational level and whether the hospitalization is voluntary or involuntary, may be important influences on ability to consent and they require further study.

6. Finally, it would be fruitful to approach research on consent by more fully meshing experimental methodology with clinical

research. Techniques can be borrowed from decision-making research and from social psychology's research methods. By utilizing more refined methodology, internal validity of our research will be enhanced. This in turn, should be balanced by the more traditional clinical studies which have greater external validity. Some attempts have been made to study consent to psychological research in this way (Bercheid et al., 1973; Farr and Seaver, 1975; Michaels and Oetting, 1979).

In conclusion, with regard to the consent process, more questions are unanswered than answered at this time. Much additional empirical work is required to answer these questions.

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Informed Consent and Competence: A Bibliography
(Special Emphasis upon Psychiatric Research)

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Contents

	Page
I. Defining the doctrine, the concept, the controversy	134
II. Determining and assessing competency and voluntariness	142
III. Understanding the process	147
IV. Improving the consent process	154
V. Issues: Right to treatment/right to refuse treatment	158

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An Agenda for Research on Competency to Consent:

A Summary of the Workshop Proceedings.

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An Agenda for Research on Competency to Consent

At the NIMH workshop on competency and the capacity to consent the participants all endorsed a call for more empirical research. It is, of course, easy to dismiss a plea for more research by researchers. I am often cynical of such positions myself. But in this case, more empirical research is not only in the best interests of researchers in the field. If properly conducted, such research could contribute significantly to important ethical and public policy questions. At the moment, our empirical understanding of the relationship between competency and consent provides a grossly inadequate base for medical decision making and for the development of reasonable public policies.

For about four hours, our group tackled the charge of developing an agenda for empirical research on competency to consent. We were asked to identify those areas where empirical research was most needed, both from a theoretical and an applied perspective. What follows is a distillation of that morning's discussion, organized around the five major areas or topics which emerged during our conversation. These areas were: comparative studies; studies of voluntariness and disclosure; studies to develop empirical tests of competency; studies to improve the consent process; and studies of proxy consent.

Comparative Studies

A particular psychiatric population's (e.g., schizophrenics) capacity to consent cannot be properly evaluated without reference to the capacities of other populations, psychiatrically impaired and otherwise. More research is needed which directly compares different groups on a series of factors including decision-making processes, decision outcomes, cognitive capacities, and comprehension of disclosed information. Examples of such studies include research which would compare (1) patients with differing psychiatric diagnosis, (2) psychiatric patients with medical patients whose illnesses involve losses of cognitive functioning (e.g., neurological and neurosurgical patients, dialysis patients), (3) psychiatric patients with chronic pain patients and otherwise seriously physically ill patients, (4) psychiatric patients with normal volunteers and (5) psychiatric patients with researchers. In addition to determining whether these groups differ in their capacities to consent, these studies should examine whether the groups differ in their personal, moral or cultural values.

Studies of Voluntariness and Disclosure

In many instances, it is difficult to distinguish issues of psychological competence from questions of voluntariness and the effects of external constraints on autonomous choice. For example, it is possible that psychiatric patients and medical patients do not differ as much in their capacity to comprehend information as in their perceptions of the consequences of refusing consent. These differing perceptions may relate to the system of involuntary civil commitment which exists for psychiatric patients, but not for medical patients. In addition, research is needed to examine the effects of institutionalization on the consent process, both for psychiatric populations and for other groups.

Issues about competency are also related to questions about disclosure. Studies are needed to determine whether psychiatric patients differ from other people in their information preferences (how much and what kinds of information they want to be told), as well as in their cognitive reactions to information. In this research, it would be particularly interesting to identify whether psychiatric patients who are being recruited as research subjects differ from investigators in their perceptions of the kinds of information that should be exchanged.

Studies to Develop Empirical Tests of Competency to Consent

There was substantial difference of opinion as to whether the field would be better served by simultaneous exploration of multiple (often conflicting) tests of competency, or by a more theoretically guided research program in which emphasis is placed on developing an acceptable definition of competency to consent. Practical considerations argue for validity and reliability testing of alternative competency scales. In this context, the issue of predictive validity was much discussed. Screening instruments designed to assess patients' capacity to understand could be validated against a criterion of actual understanding of disclosed information. Also discussed was the question of how understanding could best be operationally defined, and whether the capacity to make logical deductions from information is not central to understanding of the information.

Studies to Improve the Consent Process

In addition to studies to develop tests of competency to consent, researchers need to evaluate interventions designed to make "incompetent" patients competent. Education and communication are central to the capacity to comprehend. More research is needed to delimit the extent to which educational techniques could improve psychiatric patients' abilities to comprehend, and therefore to consent. Research is also needed to identify the costs associated with such techniques. While it may be possible with intensive enough instruction to make many or even most patients "competent," the question remains whether the result is worth the efforts. Costs to the health care system as well as the diversion of resources from the therapeutic enterprise must be considered.

Studies of Proxy Consent

Although there has been relatively little research on competency and the capacity to give consent, there has been even less research on the related practice of proxy consent. Research is needed to identify who best approximates the patient as decision maker under differing circumstances. Research is also needed to determine the kinds of people patients prefer as proxies and whether or under what circumstances proxies reach different decisions than patients.

Related to issues about proxy consent are questions about the role that family members play in the consent process, whether or not patients are viewed as competent to consent. Little is known about who actually participates in the decision to consent to research or therapy. To the extent that the decision making unit includes other individuals besides the patient (family and/or physician), judgments about the capacities of patients may be less central than judgments about the competency and autonomy of the expanded decision making unit.

Dr. Ruth Faden

APPENDIX

DHHS Regulations and Psychiatric Research: New Guidelines for Informed Consent.

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The author is speaking from her own knowledge of the regulations. The opinions expressed are those of the author and do not necessarily reflect the official policy of the National Institute of Mental Health.

New federal regulations to govern research with human subjects supported or conducted by the Department of Health and Human Services were published in the Federal Register on January 26, 1981 (1) and will go into effect on July 27, 1981. This paper will discuss those portions of the regulations which relate most directly to the critical issue of informed consent. Concern about this process has created one of the major practical problems facing research investigators working with persons whose ability to make decisions on their own behalf is not ascertained at the time of entry into consent negotiations. We have developed the phrase "persons of uncertain competence" to describe this population.

The Department has intended the regulations to be flexible enough to meet the need for any safeguards required to accomplish adequate protections for vulnerable human research subjects. With respect to the requirements for informed consent procedures, the new regulations allow substantial discretionary powers to IRBs and encourage adaptation of protective measures to suit the needs of individual protocols.

The categories of subjects identified as possibly "vulnerable" have been expanded. These now include persons with acute or severe physical or mental illness, and persons who are economically or educationally disadvantaged. (1, at 46.111 (b). Institutional Review Boards (IRBs) are also cautioned to pay special attention to research involving hospitalized patients, other institutionalized persons or disproprortionate numbers of racial or ethnic minorities or persons of low socioeconomic status. (1, p. 8378, col. 2, Par. 1)

Investigators are required to seek consent only under circumstances that minimize the possibility of coercion or undue influence and that provide prospective subjects sufficient opportunity to consider whether or not to participate. The information given must be in language understandable to the subjects (1, at 46.116). Consent must be obtained either from the subject or from the subject's legally authorized representative. No special instructions are given concerning how to determine when the representative steps in or who that individual must (or even might) be. Subjects who are adjudicated as legally incompetent will have an appointed legal guardian. For persons FUNCTIONALLY but not legally incompetent, it is usually the most available next of kin.

In cases of doubt as to functional competency, a common practice among researcher investigators is to determine that the subject understands the content of the consent form. A great deal of time and effort is spent designing and modifying consent forms to ensure that they contain at least the minimum information which subjects should have to understand in order to weigh for themselves the pros and cons, risks and benefits, of their own participation in the research.

The new regulations require eight separate elements of information to be revealed and suggest an additional six elements "when appropriate". (1, at 46.116. See Appendix). The "standard" for functional competency becomes more difficult to meet as the number of elements considered necessary for "valid" consent increases. For this reason, it is extremely important that the new regulations allow IRBs to approve consent forms which do not include, or which alter, some or all of the elements of informed consent, or to approve waiver of the requirement to obtain informed consent altogether.

This will be allowed only when:

1) the research involves no more the minimal risk
2) the waiver or alteration will not adversely affect the rights and welfare of the subjects.
3) the research could not practicably be carried out without the waiver or alteration;

AND 4) when appropriate, the subjects will be provided with additional, pertinent information after participation. (1, at 46.116 (d).

With respect to persons of "uncertain competence", e.g., persons with chronic or acute mental disabilities, victims of accidents, persons being treated with drugs which impair mental functioning, aged persons with diminished capacity, or persons of limited intelligence, the DHHS "...recognizes that individuals possess varying degrees of capacity to understand and that a particular individual's capacity can vary from time to time. Allowance for alteration or waiver of the elements of informed consent can serve as a justification for tailoring the amount and complexity of information to be provided in the consent process where potential subjects are likely to have somewhat impaired or limited capacity to understand. Under these circumstances, alterations or waivers should only be approved:

1) for use with subjects who are functionally and legally competent to give consent and
2) if the purpose is to insure that these subjects receive information they can reasonably be expected to understand in order to make a knowledgeable decision regarding their participation in the research.

In such cases, the IRB shall insure that procedures are developed to seek consent from subjects at a time when they can make a reasonable judgment, and to determine that each subject has sufficient capacity to give consent." (1, at page 8383, col. 2, Par. 1)

NOTE: These instructions are not incorporated into the body of the regulations, they appear in the preamble. However, they can and should be adopted by IRBs as standard procedure.

The implications of this new policy for psychiatric research may be to enable participation by subjects who might otherwise be considered unable to give a "valid" consent, if obliged to absorb each and every one of the required "elements". The option to tailor the content and presentation of information in order to optimize the possibility for persons to make their own decisions should enhance the self-respect and autonomy of the so-called "mentally disabled". It should also encourage much needed research by avoiding a reliance upon adversarial and "legalistic" procedures in the consent process.

Two questions immediately arise. Waivers or alterations are only allowable in "minimal risk" research with subjects who are "functionally competent". What qualifies as "minimal risk" research? How, by whom, and with what criteria shall determinations of "functional competency" be made?

The first question is more easily addressed. The new regulations define minimal risk research as research in which..."the risks of harm anticipated are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (1, at 46.102)

NOTE: "THE DHHS HAS REWORDED THE FINAL REGULATION TO REFLECT ITS INTENTION THAT THE RISKS OF HARM ORDINARILY ENCOUNTERED IN DAILY LIFE MEANS THOSE RISKS ENCOUNTERED IN THE DAILY LIVES OF THE SUBJECTS OF THE RESEARCH." (1, at p. 8373, col. 3, Par 1). Thus, an IRB might consider certain procedures to be "less than minimal risk" if they do not increase the risks to which the subject is otherwise exposed in the course of his or her daily routine.

The second question can only be answered "We don't know". Research investigators working with populations fitting the descriptive term of "uncertain competence" must begin to question and study this problem. The practical applications of the knowledge to be generated from studies of the decision-making and consent processes extend beyond the research setting. Problems emerging from implementation of the rights of institutionalized psychiatric patients to refuse treatments will be addressed through these enquiries as will problems concerning establishment of their "voluntary" or "involuntary" residency. The search for cause, prevention and treatment of mental illnesses will be much furthered by attention to these critical issues. Enhancement of the communication between subject and investigator or client and practitioner will promote the therapeutic partnership which the healing and research arts require for optimal results.

References

1. Department of Health and Human Services, Office of the Secretary, Public Health Service Human Research Subjects. Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects. Federal Register:46:16:8366, January 26, 1981.

APPENDIX DHHS REGULATIONS 45 CFR 46 Subpart A

I. INFORMED CONSENT

A. List of Required Elements: 46.116 (a)

"Except as provided elsewhere...no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

No informed consent, whether oral or written, may include any exculpatory language through which the subject (or the representative) is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

Except as provided in paragraph C, the following information shall be provided to each subject:

1) A statement that the study involves research
an explanation of the purposes of the research
the expected duration of the subject's participation
a description of the procedures to be followed
identification of any procedures which are experimental.

2) A description of any reasonably foreseeable risks or discomforts to the subject

3) A description of any benefits to the subjct or to others which may reasonably be expected from the research.

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6) FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK: An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7) An explanation of whom to contact for answers to pertinent questions about the research and subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

B. List of Optional Elements: 46.116 (b)

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3) Any additional costs to the subject that may result from participation in the research.

4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6) The approximate number of subjects involved in the study.

C. Waivers and Alteration: 46.116 (c)

An IRB may approve a consent procedure which does not include or which alters, some or all of the elements of informed consent set forth above, OR WAIVE THE REQUIREMENT TO OBTAIN INFORMED CONSENT provided the IRB finds and documents that:

1) the research is to be conducted for the purpose of demonstrating or evaluating i) Federal, state, or local benefit or service programs which are not themselves research programs,

ii) procedures for obtaining benefits or services under these programs,

OR iii) possible changes in or alternatives to these programs or procedures;

AND 2) the research could not practicably be carried out without the waiver or alteration.

"Large scale" benefit and services research.

"The Department concluded that IRB review of studies of federal, state, or local benefit or service programs is appropriate and desirable, even where it may be impracticable to obtain the informed consent of the subjects. Therefore, research of this kind will NOT be exempt from IRB review or approval requirements, BUT an IRB may approve waiver of some or all of the informed consent requirements." (FR:46:8383, Jan. 26, 1981)

OR WHEN: (46.116 (d)

1) The research involves no more than minimal risk to subjects;
2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practicably be carried out without the waiver or alteration; AND
4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

D. Documentation of Informed Consent: 46.117

Except as provided in paragraph (c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either:

1) a written consent document that embodies the elements of informed consent required by (the regulations). This form may be read to the subject or the ...legally authorized representative (and) either... (shall be given) adequate opportunity to read it before (signing).

2) a "SHORT FORM" written consent document stating that the elements of informed consent required...have been presented orally to the subject or the ...legally authorized representative.

When this (SHORT FORM) method is used, there shall be a witness to the oral presentation.

The IRB shall approve a written summary of what is to be said to the subject or the representative.

Only the short form itself is to be signed...However, the witness shall sign both the short form and a copy of the summary. The person actually obtaining the consent shall sign a copy of the summary.

A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

E. Waiver of Requirements for Documentation of Consent: 46.117 (c)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentatation linking the subject with the research, and the subject's wishes will govern.

2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

AGENDA WORKSHOP: EMPIRICAL RESEARCH ON INFORMED CONSENT WITH SUBJECTS OF UNCERTAIN COMPETENCE

January 12-13, 1981 Conference Room C, Parklawn Building

8:30 A.M. Self-Service Coffee Parklawn Cafeteria

9:00 A.M. Welcome and introduction to the workshop (15 minutes)	Natalie Reatig, Convening Chair Jerome Levine, M.D., Chief, Pharmacologic and Somatic Treatments Research Branch, NIMH
NIMH Research Policy and the Status of Federal Regulations: Informed Consent and the "Mentally Disabled" (15 minutes)	Lorraine Torres, Associate Director for Extramural Programs NIMH
Mental Health Research and Problems of Consent and Competence (10 minutes)	Louis Wienckowski, Ph.D. Director, Division of Extramural Research Programs; Acting Director, Office of Extramural Projects Review, NIMH
Questions (5 minutes)	

Prepared papers: WHAT WOULD IT MEAN TO BE COMPETENT ENOUGH TO CONSENT TO OR REFUSE PARTICIPATION IN RESEARCH?

Philosophical Overview (20 minutes)	Bernard Gert, Ph.D.
Questions for clarification (5 - 10 minutes)	
Legal Overview (20 minutes)	Alan Meisel, J.D.
Questions for clarification (5 - 10 minutes)	
Psychiatric Overview (20 minutes)	Loren Roth, M.D., M.P.H. Paul Appelbaum, M.D.
Questions for clarification (5 - 10 minutes)	
Discussion (1 hour)	Moderator: Ruth Faden, Ph.D., M.P.H.
LUNCH	Parklawn Cafeteria

Prepared paper: (20 minutes) REVIEW OF THE LITERATURE: EMPIRICAL STUDIES ON COMPETENCE AND CONSENT. Barbara Stanley, Ph.D.

Investigator reports on research in progress (1 1/2 hours)	Moderator: Natalie Reatig
Discussion (1 hour)	Moderator: Ruth Faden, Ph.D., M.P.H.
6:00 P.M. COCKTAILS AND DINNER	Bethesda Marriott Hotel Bello Mondo Restaurant

Tuesday, January 13

9:00 A.M. Developing an agenda for research (Discussion by the group)	Co-Chairs: Ruth Faden, Ph.D., M.P.H. Natalie Reatig

ADJOURNMENT APPROXIMATELY 2 P.M.

WORKSHOP: EMPIRICAL RESEARCH ON INFORMED CONSENT
WITH SUBJECTS OF UNCERTAIN COMPETENCE

January 12-13, 1981 Rockville, MD.

List of Invited Guests

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